



From the Farm to the Factory: An Overview of the American and European Approaches to Regulation of the Beef Industry

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**From the Farm to the Factory: An Overview of the American and European Approaches to
Regulation of the Beef Industry**

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I. Introduction

Over 180,000 cases of bovine spongiform encephalopathy (BSE), or mad cow disease, have been detected since the first diagnosis of the disease in 1986 in the United Kingdom¹. Outbreaks of mad cow disease have drawn considerable attention to the issue of livestock and meat regulation. Consumers are becoming more health conscious and increasingly concerned about food safety and quality. Both the United States and the European Union have put in place substantial bodies of regulations to ensure the safety and quality of the beef supply for their citizens.

In the United States, the bulk of the regulations pertaining to the beef industry are implemented by the United States Department of Agriculture (USDA), with additional regulations promulgated by the Food and Drug Administration. In many respects, state and local municipalities also contribute to the meat regulatory framework, especially in the area of health and safety inspection of meat production and processing facilities. Nevertheless, the scope of this essay is limited to federal regulatory measures.

In Europe, the Council of the European Union addresses Directives its Member States, and the Member States are given specific deadlines for the adoption of implementing legislation to incorporate the laws, regulations, and administrative provisions necessary to comply with the Directives into their national legal frameworks. Lists of the implementation deadlines for various Directives are routinely updated and published

¹Food Safety and Inspection Service, *Current Thinking on Measures that Could Be Implemented to Minimize Human Exposure to Materials that Could Potentially Contain the Bovine Spongiform Encephalopathy Agent*, NEWS AND INFORMATION (Jan. 15, 1999), at <http://www.fsis.usda.gov/OA/topics/BSE.thinking.htm>.

subsequent to the adoption of new Directives².

Considering that both the United States and the European Union face the Herculean task of regulating cattle and beef production in each of their many states and countries, respectively, many factors must be covered in their regulatory schemes. First, this paper briefly landscapes the existing regulations in both systems. Secondly, it compares the two approaches. In comparing the two systems, attention will be concentrated on the quality of legislative drafting, the likelihood of implementation, the adequacy of consumer protections, the hortatory or compulsory nature of the measures, and the requirement of record retention.

II. Animal Drug Regulations

In comparison, the United States and the European Union have different regulatory approaches regarding the rearing of livestock such as cattle. In light of the current World Trade Organization Dispute between the United States, Canada, and the European Union, much controversy surrounds the issue of trading in beef treated with growth promoting hormones. The United States and Canada, two countries that have approved the administration of growth hormones to livestock, brought an action against the European Union to determine, among other things, whether the European Union ban on beef containing growth hormones was grounded in scientific evidence that the use of hormones posed a danger to human health. This section of the paper outlines several major facets of the animal drug legislation for both the United States and the

²Council of the European Union, *Calendar for Transposition of Directives*, (Dec. 2003), at <http://europa.eu.int/comm/secretariat-general/sgb/droit.com/pdf/directive/en200312.pdf>

European Union.

A. United States Regulations on Animal Drugs Used in Meat Production

The Federal Food, Drug, and Cosmetic Act contains regulations on new animal drugs. Along with information on other animal drugs, the relevant portions of the FD&C Act provide details on permissible growth promotion hormones and their approved usage. Several specific hormones are examined in order to explore the approved quantities, methods of administration, and approved uses for such drugs³.

One of the hormones prohibited by the European Union is estradiol. Section 522.840 of the FD&C Act provides that estradiol can be administered in the form of silicone implants in either 25.7 or 43.9 milligram doses. Estradiol implantation is allowed in steers and heifers only. One 25.7 milligram implant may be used every 200 days, or one 43.9 mg implant every 400 days. The estradiol implant is used to increase weight gain in suckling and pastured growing steers, to improve feed efficiency, and to increase the rate of weight gain in confined steers and heifers. A second implant may be used if desired⁴.

Likewise, section 522.841 permits the use of estradiol benzoate in stockfarming. It may be administered for growth enhancement purposes via subcutaneous injection. 10 mg of estradiol benzoate may be administered to suckling beef calves, and 20 mg for steers and heifers fed in confinement for slaughter. Use of estradiol benzoate is prohibited on calves intended for reproduction or calves less than thirty days old⁵.

Additionally, section 522.850 authorizes the utilization of estradiol valerate and norgestomet in combination

³Section 500 of the FD&C Act can be consulted for detailed information on new animal drugs.

⁴12 U.S.C. § 522.840 (2003).

⁵12 U.S.C. § 522.841 (2003).

for synchronization of estrus or ovulation in cycling beef cattle and non-lactating dairy heifers. Pursuant to section 522.850, the implant must be removed on day ten. As implants are removed they must be collected and burned. This combination is not to be used in cows producing milk for human consumption⁶.

Other hormones, such as testosterone propionate⁷, progesterone⁸ and trenbolone acetate,⁹ can be used alone or in combination with other hormones. Although the approved hormones are administered in different ways, they have several growth promotion and production functions, including increasing weight gain, improving feed efficiency, and synchronization of estrus and ovulation. The American regulations may be contrasted with the European Union Directive below.

B. *The European Union's Prohibition on the Use of Hormonal Drugs*

On April 29, 1996, Council Directive 96/22/EC was established in order to prohibit the employment of hormonal, thyrostatic, and beta-agonist substances in stockfarming¹⁰. This directive is applicable to beef meat and meat products.¹¹ It gives details on the growth hormones that have been banned by the European Union since 1988.

Article 4 provides that Member States may authorize the therapeutic administration to livestock of testosterone, progesterone, and their derivatives that readily yield the parent compound on hydrolysis after absorption. Importantly, veterinary medicinal products must be administered by a veterinarian. They can not

⁶12 U.S.C. § 522.850 (2003).

⁷Testosterone treated beef has been banned in the European Union.

⁸Progesterone is one of the six growth hormones that is prohibited in the European Union.

⁹Trenbolone is also one of the hormones prohibited by the European Union.

¹⁰The full title of the Directive is Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having hormonal or thyrostatic action on beta-agonists.

¹¹1996 O.J. (L 125) 0003-0009.

be administered by implant, but must be administered by injection or for the treatment of ovarian dysfunction in the form of vaginal spirals. Farm animals undergoing such treatment must be clearly identified, and such treatment must be registered by the veterinarian responsible. The veterinarian must record at least the following details in a register: the type of treatment, the type of products authorized, the date of treatment, and the identity of the animal treated¹².

Additionally, Member States may authorize, for therapeutic purposes, the administration of veterinary medicinal products containing beta-agonists to induce tocolysis in cows. The above-mentioned registration measures must be followed for the administration of beta-agonists as well. Farmers are prohibited from holding veterinary medicinal products containing beta-agonists¹³.

Article 5 also allows veterinarians or their auxiliaries to administer hormonal substances for the synchronization of estrus and for the preparation of donors and recipients. However, under Article 6, the authorization of the following is prohibited: (1) hormonal products acting as a deposit; (2) products with a withdrawal period of more than fifteen days after the end of treatment; (3) products for which no reagents or equipment for detecting the presence of residues in excess of the permitted levels; and (4) veterinary medicinal products containing beta-agonists which have a withdrawal period of more than twenty-eight days after the end of treatment¹⁴.

Article 8 requires that Member States restrict the possession permissible substances to persons authorized

¹²1996 O.J. (L 125) Art. 4.

¹³1996 O.J. (L 125) Art. 4.

¹⁴1996 O.J. (L 125) Arts. 5,6.

by national legislation. The article also provides that official checks by the competent national authorities must occur without prior notice, with a view to ascertaining:

(1) the presence of prohibited substances intended to be administered for the purpose of increasing weight gain; (2) the illegal treatment of animals; and (3) failure to observe the withdrawal periods and restrictions on the use of certain substances. Further, Article 8 requires tests for the presence of the substances and residues in the drinking water of animals, in all places where animals are kept and bred, and in their excrement, body fluids, animal tissues, and products¹⁵. Article 11 prohibits the inclusion of third countries whose legislation authorizes the placing on the market and administration of stilbenes, stilbene derivatives, hormonal, thyrostatic, and beta-agonist substances to livestock on the lists of countries authorized to import farm animals, meat or meat products¹⁶.

The European Council and the European Commission amended Council Directive 96/22/EC with Council Directive 2003/74/EC in order to revise its prohibitions on the use of hormonal, thyrostatic, and beta-agonist substances in livestock farming. This amendment was made in light of the Hormones Case¹⁷, which is pending in the World Trade Organization (WTO), and the recommendations made by the WTO Dispute Settlement Body on February 13, 1998.

Article 2 of 96/22/EC has been amended to prohibit the following: (1) the placing on the market of thy-

¹⁵1996 O.J. (L 125) Art. 8.

¹⁶1996 O.J. (L 125) Art. 11.

¹⁷The Hormones Case involves a dispute settlement proceeding between the United States, Canada, and the European Union regarding the European Union's ban on beef treated with growth promoting hormones. There are six hormonal substances in question (estradiol 17 α , testosterone, progesterone, trenbolone acetate, zeranol and melengestrol acetate) whose administration for animal growth promotion purposes is prohibited by Directive 96/22/EC.

rostatic substances, stilbenes, stilbene derivatives, their salts and esters for administering to animals of all species and (2) the placing on the market of estradiol 17 α , its ester-like derivatives, and beta-agonists for administering to animals whose flesh and products are intended for human consumption. Additionally, Article 3's amendment prohibits thyrostatic substances, stilbenes, stilbene derivatives, their salts and esters, and provisionally prohibits estradiol 17 α , its ester-like derivatives, and beta-agonists¹⁸.

Article 5a was added to amend 96/22/EC. This article allows Member States to authorize the administration to farm animals of veterinary medicinal products containing estradiol 17 α or its ester-like derivatives for estrus induction in cattle until October 14, 2006. The treatment must be carried out by the veterinarian on farm animals that have been clearly identified, and the veterinarian must record the details of treatment in a register¹⁹. However, stockfarmers are prohibited from holding on their farms veterinary medicinal products containing estradiol 17 α or its ester-like derivatives²⁰.

Consistent with the European Union's position that growth stimulating hormones pose dangerous risks to humans, the European Union's Scientific Committee on Veterinary Measures relating to Public Health re-evaluated the perceived risks from residues in bovine, or beef, meat and meat products treated with growth hormones. In 1999, this independent advisory body concluded that no acceptable daily intake of hormones could be established. Based on this opinion, the European Commission has maintained its ban on the importation of beef treated with the six growth hormones²¹.

¹⁸These substances are prohibited under the following circumstances: (1) the administration of those substances to farm animals; (2) the holding, except under official control, of animals who have been administered the prohibited substance on a farm, and the placing on the market or the slaughter of such animals for human consumption; and (3) the placing on the market of meat from animals that have been administered prohibited substances. 2003 O.J. (L 262) 17-21.

¹⁹2003 O.J. (L 262) 17-21.

²⁰2003 O.J. (L 262) 17-21.

²¹Europa. *Hormones in Meat: Introduction, Food and Feed Safety* (2004), at http://europa.eu.int/comm/food/food/chemicalsafety/contaminants/hormones/index_en.htm.

III. Organic Livestock Production

One alternative to purchasing beef treated with growth hormones is the purchase of organically produced beef. In recent years, consumer demand for organic products has risen greatly. While all agricultural products are covered by safety and quality guarantees, organically produced beef must fulfill additional production criteria. The next section describes the American and the European Union's approach to regulating organic livestock production.

A. United States Rules on Organic Livestock Farming

The Organic Foods Production Act (OFPA) of 1990 was promulgated in order to establish national standards governing the marketing of certain agricultural goods as organically produced products. The OFPA seeks to assure consumers that organically produced products meet a consistent standard²².

Section 6503 of the OFPA Act enables the Secretary of Agriculture to establish a national certification program for producers and handlers of agricultural products that have been produced using organic methods²³. The Agriculture Secretary can also permit each state to implement its own organic certification program for producers and handlers of agricultural products that have been produced using organic methods. The program must be implemented through certifying agents, who may certify a farm or handling operation as

²²Organic Foods Production Act of 1990, 7 U.S.C. § 6501 (2003).

²³Organic Foods Production Act of 1990, 7 U.S. § 6503 (2003).

organically certified. To be sold or labeled as an organically produced agricultural product, an agricultural product must have been produced and handled without the use of synthetic chemicals²⁴.

Under section 6505, a label may be affixed to organically certified domestic agricultural products for the purpose of indicating that they comply with United States Department of Agriculture (USDA) standards for organic production. Such labels may incorporate the Department of Agriculture seal. Imported agricultural products may be sold or labeled as organically produces if the Secretary determines that such products have been produced and handled under an organic certification program that is equivalent to the requirements laid down for products in the United States²⁵.

Under section 6506, an organic certification program is required to provide that an agricultural product to be sold or labeled as organically produced must: (1) be produced only on certified organic farms and handling operations; (2) require that producers and handlers establish an organic plan; (3) require each certified organic farm or handler to certify to the Secretary, the State official, and the certifying agent on an annual basis that all agricultural products have been produced organically; (4) provide for annual on-site inspection by the certifying agent of each farm and handling operation; (5) require periodic residue testing by certifying agents of agricultural products produced on certified organic farms and in handling operations to determine whether they contain any pesticide or other nonorganic residue; and (5) provide for public access to certifying documents and laboratory analyses that pertain to certification²⁶.

Any livestock that is to be slaughtered and sold or labeled as organically produced must be raised in accordance with the proceeding directives as established in section 6509. Livestock farms must feed the

²⁴Organic Foods Production Act of 1990, 7 U.S. § 6503 (2003).

²⁵Organic Foods Production Act of 1990, 7 U.S. § 6505 (2003).

²⁶Organic Foods Production Act of 1990, 7 U.S. § 6506 (2003).

livestock organically produced feed. The farms are prohibited from using growth promoters and hormones on livestock, including antibiotics and synthetic trace elements used to stimulate growth or production.

Furthermore, livestock produced by organic farm producers must not use subtherapeutic doses of antibiotics, synthetic internal parasiticides on a routine basis, or administer medicine other than vaccines, in the absence of illness. In order to facilitate livestock identification, organic livestock producers are required to keep adequate records and maintain verifiable audit trails so that each animal can be traced back to the farm. The records must specifically contain details on the amounts and sources of medications administered and all feeds fed to the livestock²⁷. Producers must maintain records for five years concerning the production or handling of organically produced agricultural products²⁸.

B. *European Union Regulation of Organically Produced Livestock*

On July 19, 1999, the European Council drafted Regulation No. 1804/1999²⁹, which is a supplement to Regulation No. 209/91, in order to prescribe rules for the organic production of livestock³⁰. This supplemental regulation pertains to livestock and livestock products from bovine animals that are intended for human consumption³¹.

Under section B.1.3 of this Regulation, organic production requires stockfarming methods that use renewable natural resources, such as livestock manure, legumes, and fodder crops. Organic stockfarming to maintain

²⁷Organic Foods Production Act of 1990, 7 U.S. § 6509 (2003).

²⁸Organic Foods Production Act of 1990, 7 U.S. § 6511 (2003).

²⁹The full title of this Regulation is Council Regulation (EC) No 1804/1999 of 19 July 1999 supplementing Regulation (EEC) No 209/91 on organic production of agricultural products and indications referring thereto on agricultural products and foodstuffs to include livestock production.

³⁰1999 O.J. (L 222) 24.8.1999.

³¹The Regulation does not apply exclusively to bovines. It also applies to swine, poultry and other livestock.

the soil fertility utilizes the cropping/stockfarming system and the pasturage system. Section B.1.4 stipulates that organic stockfarming requires that animals have access to a free-range area and the number of animals per unit must be limited to ensure integrated management of livestock and crop production on the production unit³².

Conversion of livestock associated with organic livestock production is allowed under section 2. In order to convert them, livestock from which organic products are derived must be reared as such for at least twelve months in the case of bovines for meat production. Similarly, conversion occurs if livestock marketed as organically produced are reared as such for six months in the case of animals for milk production³³. Although section 3.2 provides that organic production systems must be applied throughout the life of the livestock, section 3.3 establishes that livestock not complying with organic rules of production can be converted in the specified time periods³⁴.

In connection with the organic production of livestock for human consumption, feed is intended to ensure quality rather than maximize production. However, fattening processes are authorized if they are reversible at any stage of the rearing process. Livestock must be fed organically produced feed, and young bovine animals must be fed natural milk, preferably maternal milk, for a period of three months. Rearing systems for herbivores are to be based on pasturage. At least sixty percent of the dry matter in daily rations must consist of roughage, fresh or dried fodder, or silage³⁵.

Furthermore, vitamins and minerals can be fed to animals. On the contrary, antibiotics, coccidiostatics,

³²1999 O.J. (L 222) 24.8.1999.

³³1999 O.J. (L 222) 24.8.1999.

³⁴1999 O.J. (L 222) 24.8.1999.

³⁵1999 O.J. (L 222) 24.8.1999.

medicinal substances, growth promoters, or any other substance intended to stimulate growth or production can not be used in animal feeding. Moreover, animal feed must not have been produced with genetically modified organisms or products derived from such organisms³⁶.

In connection with organic production, disease prevention and veterinary treatment of organic animals should be performed under certain guidelines. Particularly, disease prevention in organic livestock production must adhere to the following principles: (1) selection of appropriate breeds and strains of animals; (2) the application of animal husbandry practices appropriate to encourage strong resistance to disease and infections; (3) the use of high quality feed, regular exercise, and access to pasturage to encourage natural immunological defenses; and (4) avoidance of livestock overstocking³⁷.

The aforementioned principles are intended to limit animal health problems so they can be controlled primarily through prevention. Nevertheless, sick or injured animals must be treated immediately. Certain veterinary medicinal products should be used in organic farming. For example, phytotherapeutic, homeopathic, and trace elements may be used in preference to chemically synthesized allopathic medicinal products or antibiotics. The latter may be administered by a veterinarian if necessary to combat illness or treat injury. The use of chemically synthesized allopathic veterinary medicinal products and antibiotics is prohibited. Further, the use of substances to promote growth or production, such as antibiotics, coccidiostatics, and other growth enhancers, the use of hormones or similar substances to induce or synchronize estrus is prohibited. Hormones may be administered to an individual animal for therapeutic treatment³⁸.

Whenever veterinary products are used, the product type and details of the diagnosis and treatment must

³⁶1999 O.J. (L 222) 24.8.1999.

³⁷1999 O.J. (L 222) 24.8.1999.

³⁸1999 O.J. (L 222) 24.8.1999.

be recorded. The legal withdrawal period must also be recorded. This information is to be declared to the inspection authority before the livestock or livestock products are marketed as organically produced. In addition, livestock that has been treated must be clearly identified³⁹.

With the exception of vaccinations, treatments for parasites, and any compulsory eradication schemes, livestock and livestock products that have received more than three courses of treatments with chemically synthesized allopathic medicinal products or antibiotics within one year may not be sold as organic products. The livestock must undergo conversion periods subject to the agreement of the inspection authority.

Some additional rules for organic livestock include the following.

Regarding husbandry, the reproduction of organic livestock should be natural as a matter of principle. However, artificial insemination is permitted. Also, keeping livestock tethered is forbidden unless it is for limited time periods as authorized by the inspection authority for health or safety reasons. In addition, insulation, heating, and ventilation of the livestock housing facilities must ensure that air circulation, dust level, temperature, and relative humidity are kept within safe limits. On top of that free-range and open air exercise areas must provide sufficient protection from rain, wind, sun, and extreme temperatures⁴⁰.

The European Union's rules encourage rearing practices that safeguard the health and welfare of the animals as well as the consumer. Beef bearing the European Union logo for organic farming is guaranteed to have been produced under strict guidelines. Member States are free to impose more rigid standards on organic beef produced in their territory.

³⁹1999 O.J. (L 222) 24.8.1999.

⁴⁰1999 O.J. (L 222) 24.8.1999.

IV. Humane Methods of Slaughter

Both the United States and the European Union have enacted legislative provisions that speak to their commitment to the humane slaughtering of livestock. The regulations place the avoidance of needless suffering on the radar for beef and beef product producers. It is interesting to note that special provisions for religious or ritual slaughter are made in both instruments. Important provisions from both legislative frameworks are outlined below.

A. The United States Humane Slaughter Act

Section 603(b) of the Federal Meat Inspection Act provides that the Secretary of Agriculture is charged with the duty of authorizing the appointment of inspectors to examine slaughtering methods in slaughtering establishments as a means of preventing the inhumane slaughter of livestock. Moreover, the United States Congress has explicitly declared that slaughtering and handling of livestock in connection with slaughter is to be carried out only by humane methods. Humane methods of slaughter prevent needless suffering, result in safer and better working conditions for the persons employed in the slaughter industry, and improve products and economies in slaughtering operations. In furtherance of its policy for humane slaughtering of livestock, Congress enacted the Humane Slaughter Act of 1958⁴¹.

In section 1902, Congress has enumerated the methods of slaughter found to be humane. In the case of

⁴¹7 U.S.C.A. § 1901-1907 (2004).

cattle and calves⁴², animals are rendered insensible to pain by a single blow, gunshot, electrical, or chemical means that is rapid and effective. This stunning must occur before the livestock is shackled, hoisted, thrown, cast, or cut. In addition, this Act authorizes slaughtering in accordance with the ritual requirements of the Jewish faith or any other religious faith that prescribes a method of slaughter in which the animal suffers loss of consciousness by anemia of the brain caused by the simultaneous and instantaneous severance of the carotid arteries.⁴³

Under section 1904, the Secretary of Agriculture is authorized and directed to conduct research and experimentation using current methods and scientific knowledge to develop methods of slaughter and handling of livestock in connection with slaughter that are practicable in speed and scope of operations and humane⁴⁴. Section 1906 contains the caveat that nothing in the Humane Slaughter Act is intended to be construed to prohibit or hinder the religious freedom of any person or group. In order to protect religious freedom, ritual slaughter and the handling and preparation of livestock for ritual slaughter are exempted from the terms⁴⁵. Similar provisions are found in the European Union instrument on humane methods of livestock slaughter.

B. European Union Rules on Humane Methods of Slaughter

Council Directive 93/119/EC was established in 1993 to set forth a framework of rules on the humane slaughter of animals⁴⁶. Annex A of this Directive clearly details the rules to be

⁴²The Humane Slaughter Act also applies to horses, mules, sheep, swine, and other livestock.

⁴³7 U.S.C.A. § 1902 (2004).

⁴⁴7 U.S.C.A. § 1904 (2004).

⁴⁵7 U.S.C.A. § 1906 (2004).

⁴⁶1993 O.J. (L 340) 31.12.1993.

implemented by Member States. These rules apply to cattle, among other animals.

With the aim of avoiding unnecessary pain and suffering, Annex A provides that animals in slaughterhouses must be protected from extreme weather, and the condition of the animals must be inspected at least every morning and evening. In addition, non-ambulatory animals must not be dragged to slaughter. Instead, such animals must be killed where they lie or transported on a trolley to a place of emergency slaughter. Unloading equipment must have non-slip flooring and railings to prevent animals from falling, and animals must not be lifted by the head, horns, ears, feet, or tail. Additionally, blows and kicks to animals are prohibited⁴⁷.

Annex A goes on to establish that drinking water must always be available to animals that are not slaughtered immediately upon arrival in the slaughtering facility. Animals that have not been slaughtered within twelve hours of their arrival must be fed at appropriate intervals, and animals kept more than twelve hours at a slaughterhouse must be lairaged⁴⁸.

Annex B lays out rules for restraint of animals before stunning and slaughter. Accordingly, animals must be restrained such that unnecessary pain, suffering or injury is avoided. Particularly, animals' legs must not be tied, and animals must not be suspended before stunning or killing. In the case of ritual slaughter, restraint of bovine animals before slaughter using a mechanical method intended to avoid pain, suffering, or injuries to the animals is obligatory⁴⁹.

Under Annex C, the following methods of stunning are permitted:

⁴⁷1993 O.J. (L 340) 31.12.1993.

⁴⁸1993 O.J. (L 340) 31.12.1993.

⁴⁹1993 O.J. (L 340) 31.12.1993.

captive bolt pistol fired into cerebral cortex; (b) concussion using a mechanically-operated instrument that strikes the skull without fracturing it; and (c) electronarcosis in which currents pass through the brain. Stunning must not be carried out unless it is possible to bleed the animals immediately afterwards. Annex C also establishes that cattle may be slaughtered with the use of a free bullet pistol or rifle, electrocution, and carbon dioxide gas⁵⁰.

V. Regulations on BSE and Other Contagious Diseases

Those familiar to the cattle industry can attest that infectious diseases, which have decimated entire herds and spread to other livestock and humans as well, have presented the industry with formidable challenges for many years prior to the advent of BSE. Strict measures have been implemented in the United States and the European Union for the purpose of curtailing the spread of communicable livestock diseases and the contamination of the human food supply. This portion of the paper details the regulations on the spread of diseases that affect the beef industry.

A. United States Regulations on BSE and Other Livestock Diseases

⁵⁰1993 O.J. (L 340) 31.12.1993.

Before BSE, other diseases infected cattle and threatened the wholesomeness of beef and beef products. In response to this problem, the Cattle Contagious Diseases Act (CCDA) was enacted in 1903. The purpose of the enactment was to curtail the spread of livestock diseases and to protect the meat supply⁵¹.

Section 113 of the CCDA authorizes the Secretary of Agriculture to adopt measures to prevent the exportation from any port in the United States to any port in a foreign country of livestock affected with any communicable disease. Transportation from one State to another State of any livestock affected with a contagious, infectious, or communicable disease is prohibited, unless such transportation is for the purpose of slaughtering the diseased animals⁵². Section 114 (a) is an example of the mandates created to prevent the spread of contagious livestock diseases from one State to another State. For instance, with respect to tuberculosis and brucellosis, domestic animals that have reacted positively to a test for paratuberculosis or brucellosis may be shipped from one State to any other State for immediate slaughter. Similar provisions exist in the CCDA for other contagious diseases. The animals must be tested for the commonly known diseases according to pre-established testing methods. Livestock that test positive for infectious diseases and diseases harmful to humans must be slaughtered immediately⁵³.

In addition to those contained in the CCDA, regulations have been promulgated to ensure the identification of animals destroyed because of tuberculosis for indemnification purposes. Cattle are classified as infected with tuberculosis on the basis of an intradermal tuberculin test applied by a Federal, State, or otherwise accredited veterinarian⁵⁴.

⁵¹21 U.S.C. § 112-122 (2004).

⁵²21 U.S.C. § 115 (2004).

⁵³21 U.S.C. § 114(a) (2004).

⁵⁴9 C.F.R. § 50.4(a) (2004).

Pursuant to 9 C.F.R. § 50.6(a), livestock destroyed because of tuberculosis must be identified as follows: (1) livestock⁵⁵ classified as reactors for tuberculosis must be identified within fifteen days after being classified as reactors; (2) reactor cattle must be identified by branding the letter “T” on the left hip and by attaching to the left ear an approved metal ear tag bearing a serial number and the inscription “U.S. Reactor;”

(3) exposed cattle must be identified by branding the letter “S” on the left hip and by attaching to either ear a metal ear tag bearing a serial number⁵⁶.

Under section 50.7, livestock to be destroyed because of tuberculosis must be given a permit to be shipped directly to slaughter at a Federal or State inspected slaughtering establishment or be disposed of by rendering, burial, or incineration⁵⁷. Livestock for which federal indemnity may be paid because of tuberculosis must be destroyed and disposed of within fifteen days after the date of appraisal, unless the veterinarian in charge extends the time limit for slaughter to thirty days⁵⁸.

Animals infected with or exposed to a communicable disease must be slaughtered promptly after appraisal and disposed of by burial or burning, unless otherwise provided by the Administrator at his or her discretion. An Animal and Plant Health Inspection Service (APHIS) employee must supervise the slaughter and disposal.

The official administrator is authorized to agree, on behalf of the United States Department of Agriculture, to pay 50 percent of the expense of purchase, destruction, and disposition of animals that must be destroyed because of a communicable disease⁵⁹.

⁵⁵This title refers to cattle, bison, captive cervids, and other animals.

⁵⁶9 C.F.R. § 50.6 (2004).

⁵⁷9 C.F.R. § 50.7(a) (2004).

⁵⁸9 C.F.R. § 50.7(b) (2004).

⁵⁹9 C.F.R. § 53.2 (2004).

Under 7 U.S.C. § 8306, the Secretary of Agriculture may hold, seize, quarantine, treat, destroy, dispose of any animal that the Secretary has reason to believe may carry, may have carried, or may have been affected with or exposed to any pest or disease of livestock at the time of movement⁶⁰. Similarly, if the Secretary determines that an extraordinary emergency exists due to the presence in the United States of a pest or disease of livestock and that the presence of such threatens the livestock of the United States, the Secretary may hold, seize, treat, destroy, or dispose of any animal or article. The Secretary may also prohibit or restrict the movement within the United States of any animal or article in order to prevent the dissemination of the pest or disease⁶¹.

B. Measures for the Detection and Eradication of Bovine Spongiform Encephalopathy

Since the initial detection of BSE in 1986, the United States government has implemented various measures to prevent BSE from entering the U.S. and to prevent the spread of the disease in the event of its introduction into the U.S.⁶². For example, since 1989, the United States Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) has banned the importation of live cattle and cattle products, such as rendered protein products, from countries where BSE exists. Specifically, in 1989, the USDA banned the importation of live ruminants and ruminant products from the United Kingdom. Then, in 1997, APHIS extended the application of these import restrictions to all European countries because of concerns about widespread risk factors and what APHIS believes to be inadequate surveillance for BSE in many European countries⁶³.

⁶⁰7 U.S.C. 8306(a) (2003).

⁶¹7 U.S.C. 8306(b) (2003).

⁶²These measures were set forth by the United States Department of Agriculture and the Food and Drug Administration.

⁶³Food Safety and Inspection Service, *Current Thinking on Measures that Could Be Implemented to Minimize Human Exposure to Materials that Could Potentially Contain the Bovine Spongiform Encephalopathy Agent*, NEWS AND INFORMATION (Jan. 15, 1999), at http://www.fsis.usda.gov/OA/topics/BSE_thinking.htm.

Beginning in December 7, 2000, APHIS implemented a prohibition on imports of rendered animal protein products, irrespective of species, from BSE-restricted countries. This ban resulted from apprehension that feed intended for cattle may have been cross-contaminated with the BSE agent. Similarly, in 1997, Food and Drug Administration prohibited the use of certain mammalian protein in the manufacture of ruminant animal feed. Under this prohibition, firms must do the following: (1) keep specified records on the manufacture of their feed, (2) prohibit co-mingling between ruminant feed and non-ruminant feed containing materials prohibited in ruminant feed, and (3) must assure that non-ruminant feed containing materials prohibited in ruminant feed is labeled conspicuously with the statement *Do not feed to cattle and other ruminants*. The purpose of these regulations is to prevent the introduction and spread of BSE to American cattle through contaminated feed⁶⁴.

APHIS also operates an interagency surveillance system for BSE in the U.S. In conjunction with the Food Safety and Inspection Service (FSIS), APHIS has constructed an emergency response plan for use in the event of BSE detection in the United States. Furthermore, other Federal agencies have created contingency plans that work alongside the USDA plan. In particular, the Centers for Disease Control and Prevention (CDC) runs a surveillance system for variant Creutzfeldt-Jakob Disease (vCJD), a fatal neurodegenerative disease that affects humans and is linked to the consumption of BSE-contaminated beef products⁶⁵.

Since the detection of BSE in Canada in May 2003, the USDA has initiated additional mea-

⁶⁴Food Safety and Inspection Service, *Current Thinking on Measures that Could Be Implemented to Minimize Human Exposure to Materials that Could Potentially Contain the Bovine Spongiform Encephalopathy Agent*, NEWS AND INFORMATION (Jan. 15, 1999), at http://www.fsis.usda.gov/OA/topics/BSE_thinking.htm.

⁶⁵Food Safety and Inspection Service, *Current Thinking on Measures that Could Be Implemented to Minimize Human Exposure to Materials that Could Potentially Contain the Bovine Spongiform Encephalopathy Agent*, NEWS AND INFORMATION (Jan. 15, 1999), at http://www.fsis.usda.gov/OA/topics/BSE_thinking.htm.

asures, consistent with those taken by Canada, to improve protections against BSE. In this respect, the USDA has undertaken the immediate implementation of a verifiable system of national animal identification to accomplish across the board uniformity and efficiency in the current national systems. Additionally, the USDA has banned the use of all “downer⁶⁶” cattle as human food. Surveillance data from European countries where BSE has been found indicate that cattle with clinical signs of a central nervous system disorder, dead cattle, and downer cattle have a greater incidence of BSE⁶⁷.

USDA Food Safety and Inspection Service inspectors must wait to mark cattle tested for BSE as “Inspected and passed” until receipt of confirmation that the animals have tested negative for BSE. Also, the USDA has designated specified risk materials, namely the skull, brain, trigeminal ganglia, eyes, vertebral column, spinal cord and dorsal root ganglia of cattle over thirty months of age and the small intestine of cattle of all ages. Human consumption of special risk material will be prohibited. Tonsils from all cattle are already considered inedible and therefore do not enter the food supply⁶⁸.

The FSIS will require federally inspected establishments that slaughter cattle to develop, implement, and maintain procedures to remove, segregate, and dispose of these specified risk materials to preclude their entrance into the human food supply. Meat production establishments must make records of this information available for review by FSIS inspection personnel. The FSIS has also developed methods for verifying the age of cattle that are slaughtered in official establishments, and they require state inspected plants to establish

⁶⁶“Downer” cattle are unable to walk or rise from a recumbent position.

⁶⁷**United States Department of Agriculture**, *Veneman Announces Additional Protection Measures to Guard Against BSE*, USDA NEWS RELEASE (Dec. 30, 2003), at <http://www.usda.gov/news/releases/2003/12/0449.htm>.

⁶⁸2001 O.J. (L 147) Ann. 5.

equivalent procedures⁶⁹. These measures have been implemented because most of the cattle that have tested positive for BSE have been at least thirty months of age.

Further, the FSIS has regulated the advanced meat recovery (AMR) process in order to protect the meat supply from disease contamination. AMR is a technological method that removes muscle tissue from the bone of beef carcasses under high pressure without incorporating bone material. The FSIS has expanded the regulation prohibiting the inclusion of the spinal cord in AMR products labeled as “meat.” Now, the prohibition will ban the inclusion of dorsal root ganglia and nerve clusters connected to the spinal cord. Like the spinal cord, the dorsal root ganglia may also contain BSE agents. In addition, the vertebral column and the skull in cattle thirty months and older is inedible and can not be used for AMR⁷⁰.

C. The European Union Rules on Transmissible Spongiform Encephalopathy

The European Union’s provisions for the control of contagious diseases are often folded into legislation that encompasses a wider range of topics. However, the European Union has enacted specific rules in at least one case. On May 22, 2001, the European Parliament and the European Council passed Regulation No. 999/2001, and amendment to prior regulations, to address the eruption of certain transmissible spongiform encephalopathies (TSEs), including bovine spongiform encephalopathy (BSE) or mad cow disease⁷¹. This regulation applies to the production, placing on the market, and exportation of live animals and products of animal origin. Where cases of TSEs are confirmed, Member States are required to draft guidelines specifying

⁶⁹Food Safety and Inspection Service, *Current Thinking on Measures that Could Be Implemented to Minimize Human Exposure to Materials that Could Potentially Contain the Bovine Spongiform Encephalopathy Agent*, NEWS AND INFORMATION (Jan. 15, 1999), at http://www.fsis.usda.gov/OA/topics/BSE_thinking.htm.

⁷⁰Food Safety and Inspection Service, *Current Thinking on Measures that Could Be Implemented to Minimize Human Exposure to Materials that Could Potentially Contain the Bovine Spongiform Encephalopathy Agent*, NEWS AND INFORMATION (Jan. 15, 1999), at http://www.fsis.usda.gov/OA/topics/BSE_thinking.htm.

⁷¹1996 O.J. (L 125) 0010-0032.

the national measures to be implemented and indicating responsibilities in accordance with the Community rules⁷².

Annex II of this Regulation lays down the criteria for the determination of BSE status of a Member State, third country, or their regions. BSE status is to be determined based on multiple factors. One factor is the outcome of a risk analysis that considers the following factors: (1) whether bovine animals consume meat and bone meal or greaves derived from ruminants; (2) whether meat and bone meal or greaves are potentially contaminated by a transmissible spongiform encephalopathy (TSE) or animal feed containing meat and bone meal or greaves is imported; (3) whether animals or ova/embryos potentially infected by a TSE are imported; (d) the epidemiological status of a country or region in regard to animal TSEs; (e) the extent of knowledge about the structure of the bovine population in the country or region; and (f) the source of animal waste, the processes for treating such waste, and the methods of producing animal feed⁷³.

A second factor of consideration is whether the Member State, third country, or regions operate an education program that encourages veterinarians, breeders, and those who transport, trade, and slaughter bovine animals to report all cases of neurological manifestations in adult bovine animals. A third important factor in determining BSE status is whether the compulsory reporting and examination of all bovine animals showing clinical signs of BSE is mandated, and whether a system of continuous surveillance and monitoring of BSE with an obligation to retain the results for seven years is implemented. Another factor is whether the Member State, third country, or region requires examination of encephala or other tissues collected under the surveillance system in an approved laboratory⁷⁴.

⁷²2001 O.J. (L 147) Arts. 1,14.

⁷³2001 O.J. (L 147) Ann. 2.

⁷⁴2001 O.J. (L 147) Ann. 2.

The BSE status of countries or regions is to be determined by classification into the following five categories:

(1) Category 1: Country or Region free of BSE; (2) Category 2: BSE provisionally free country or region where no indigenous case has been reported; (3) Category 3: BSE provisionally free country where at least one case of BSE has been reported; (4) Category 4: Country or Region with low incidence of BSE; and (5) Category 5: Country or Region with high incidence of BSE⁷⁵.

In addition, Annex 3 establishes a system with minimum requirements for monitoring BSE in bovines⁷⁶.

Under this scheme, each Member State carries out an annual program for monitoring BSE, which includes rapid post mortem screening. Such screening must be performed on: (1) all bovine animals subject to special emergency slaughtering or showing signs of any form of disease at the time of ante mortem inspection at the slaughterhouse; (2) all bovine animals over thirty months of age slaughtered normally for human consumption; (3) dead bovine animals that are not slaughtered for human consumption and that are found dead on the farm or during transport; (4) all animals slaughtered for human consumption; and (5) bovine animals displaying a neurological disorder⁷⁷.

Member States may voluntarily carry out targeted surveillance for TSE in higher risk animals. Higher risk animals include those animals originating from countries with indigenous TSE, animals that have consumed potentially contaminated foodstuffs, and animals born or derived from TSE-infected cattle. Additionally, Member States must ensure that no parts of the body of animals being screened for TSE are used for human food, animal feed, or fertilizers until the laboratory examination has been concluded with negative results⁷⁸.

⁷⁵2001 O.J. (L 147) Ann. 3.

⁷⁶The system also monitors for scrapie in other animals.

⁷⁷2001 O.J. (L 147) Ann. 3.

⁷⁸2001 O.J. (L 147) Ann. 3.

Member States must submit reports on all detected cases of TSE to the European Commission. The information reported must entail the number, age distribution, geographical distribution of positive cases of BSE, as well as the year and month of birth should be given for BSE cases born after the introduction of a ban on using ruminant protein in animal feed⁷⁹. Annex 4 provides that Member States or regions grouped into Category 5 are prohibited from feeding ruminant animals protein derived from mammals. Under this prohibition, farm animals must not be fed protein derived from mammals. Furthermore, Member States and regions are prohibited from feeding ruminants the fat rendered from ruminants⁸⁰.

Depending on the category of the country or region, Annex 5 has designated the following tissues as specified risk material. As regards Categories 3 and 4, the skull, brain, eyes, tonsils, spinal cord of animals over twelve months old, and the intestines of bovines of all ages are deemed specified risk material. With Respect to Category 5, the entire head, tongue, brain, eyes, trigeminal ganglia, tonsils, thymus, spleen, and spinal cord of bovine animals over six months old, and the intestines of animals of all ages are classified as specified risk material. All specified risk material must be removed at slaughterhouses, cutting plants, or similar premises under the supervision of an agent appointed by the competent authority. All specified risk material must also be marked upon removal for identification purposes and immediately destroyed by incineration or burial in an approved landfill⁸¹.

Article 13 provides for the eradication of TSEs. When the presence of a TSE has been officially confirmed, the following measures must be taken: (1) all of the animal's body parts must be completely destroyed; (2) an inquiry must be carried out to identify all animals at risk; (3) an inquiry must be performed to identify all embryos, ova, and the last progeny of a female animal in which the disease has been confirmed and the

⁷⁹2001 O.J. (L 147) Ann. 3.

⁸⁰2001 O.J. (L 147) Ann. 4.

⁸¹2001 O.J. (L 147) Ann. 5.

embryos or progeny of collected or born up two years prior to or after the clinical onset of the disease; and

(4) all animals and products of animal origin that have been identified as specified risk materials must be destroyed. Owners must be compensated for the loss of animals that have been killed or products of animal origin that have been destroyed pursuant to this Directive⁸².

In connection with the eradication of TSEs, Annex 7 lays out additional terms. It requires the performance of an inquiry to identify the possible origin of the disease and other farms and holdings on which there are animals, embryos, or ova that may have become infected by TSE or exposed to the same feed or contamination source. The inquiry must also endeavor to pinpoint the movement of potentially contaminated foodstuffs or any other contamination sources⁸³.

Annex 8 established provisions for the intra-Community trade of live animals, embryos, and ova. It provides that bovine embryos and ova must be derived from females that are not suspected of TSE infection at the time of collection. This condition applies to the movement of bovine embryos and ova irrespective of the category of the Member State, third country, or region⁸⁴.

The following conditions apply to movements of bovine animals coming from Member States, depending on the category of the State. As regards Categories 3 and 4, animals must have been born and raised in herds with no case of confirmed BSE for at least seven years, or have been born after the date from which the prohibition on the feeding of ruminants with protein derived from mammals has been effectively enforced. With respect to Category 5, the animals must have been born after the date from which the ban on the

⁸²2001 O.J. (L 147) Ann. 5.

⁸³2001 O.J. (L 147) Ann. 7.

⁸⁴2001 O.J. (L 147) Ann. 8.

feeding of ruminants with protein derived from mammals has been effectively enforced and have been born and raised in herds with no case of confirmed BSE for at least seven years⁸⁵.

Healthy live animals, their semen, embryos, and ova may be placed on the market, provided that such articles are accompanied by animal health certificates. Products of animal origin derived from healthy animals may also be placed on the market⁸⁶. Annex 9 contains similar provisions in the context of exportation outside the European Community.

Annex 10 establishes the guidelines for national reference laboratories, which are designated in order to ensure the uniformity of scientific analysis and reliable results. The national reference laboratories must be able to confirm the results of regional laboratories, to identify the type and strain of TSE when the disease is diagnosed, to verify diagnostic methods used in regional laboratories, and to refer unidentifiable strains of TSE to the Community reference laboratory⁸⁷. In addition, the Community reference laboratory for TSE, or the Veterinary Laboratories Agency, is responsible for coordinating the methods employed in the Member States for diagnosing BSE and facilitating the training of diagnostic experts in order to harmonize diagnostic techniques throughout the Community⁸⁸.

VI. Inspection of Live Cattle, Beef, Beef Food Products and Beef Production Establishments

⁸⁵2001 O.J. (L 147) Ann. 8.

⁸⁶2001 O.J. (L 147) Ann. 8.

⁸⁷2001 O.J. (L 147) Ann. 10.

⁸⁸2001 O.J. (L 147) Ann. 10.

Much importance is placed on the inspection stage of regulatory process, because inspection is the best way to ensure that unsafe and unwholesome beef and beef products do not enter the human food chain. Conscientious maintenance of quality and safety standards must be monitored under reliable and trustworthy conditions. Both the United States and the European Union require official inspectors to perform on-site checks of farms and meat production plants. A summary of the inspection regulations follows.

A. The United States Federal Meat Inspection Act

In the interest of protecting the health and welfare of consumers and preserving the market for meat, Congress passed the Federal Meat Inspection Act (FMIA) to ensure that wholesome, unadulterated⁸⁹, properly packaged and labeled meat and meat food products enter interstate and foreign commerce⁹⁰. This segment will summarize the regulations set forth by the FMIA as they pertain to cattle⁹¹.

In order to prevent the use in commerce of adulterated meat and meat food products, section 603(a) empowers the Secretary of Agriculture to authorize the appointment of inspectors to examine and inspect cattle before they are allowed to enter into any slaughtering, packing, meat-canning, rendering, or similar establishment. Upon inspection, all cattle found to show symptoms of disease are to be slaughtered separately from healthy cattle.

Further, the Secretary must authorize the appointment of inspectors to conduct post mortem inspections of carcasses and parts of carcasses to be prepared at any slaughtering, meat-canning, salting, packing, rendering,

⁸⁹The term “adulterated” refers to the condition of a carcass, meat, or meat food product that contains a poisonous or deleterious substance in a quantity that may render it injurious to health.

⁹⁰21 U.S.C. 602 (2004).

⁹¹The FMIA regulates the inspection of meats derived from cattle, sheep, swine, goats, horses, mules and other equines.

or similar establishment in any State, Territory, or the District of Columbia as articles of commerce to be used as human food. The carcasses and parts found not to be adulterated must be stamped as “Inspected and passed.” Carcasses and parts found to be adulterated are to be stamped as “Inspected and condemned.” Section 604 necessitates the destruction of all condemned carcasses intended to be used as human food⁹².

Carcasses and parts of carcasses, the meat, or meat products of such carcasses must be inspected and examined before they are allowed to enter into any slaughtering, meat-canning, salting, packing, rendering, or similar establishment in which they will be prepared for meat food products. Any such products, which after leaving any slaughtering, meat-canning, salting, packing, rendering, or similar establishment are returned to the same establishment, must also be inspected⁹³.

Pursuant to section 606 of the FMIA, the Secretary of Agriculture authorizes the appointment of inspectors to examine and inspect all meat food products prepared for commerce and export in any slaughtering, meat-canning, salting, packing, rendering, or similar establishment. In order to carry out their inspection duties as mandated by this law, inspectors must be granted access at all times to every part of the establishment. Inspectors must mark all unadulterated meat food products “Inspected and passed” and all adulterated food products “Inspected and condemned⁹⁴.” Furthermore, false or misleading marking or labeling on meat food intended for sale is prohibited under section 607⁹⁵.

⁹²21 U.S.C. § 604 (2004).

⁹³21 U.S.C. § 605 (2004).

⁹⁴21 U.S.C § 606 (2004).

⁹⁵21 U.S.C § 607 (2004).

Under authorization of the Agriculture Secretary, competent inspectors must perform sanitation inspections of all slaughterhouses, meat-canning, salting, packing, rendering, or similar establishments where cattle are slaughtered and the meat and meat food products are prepared for commerce⁹⁶. The inspections must be carried out with the aim of prescribing appropriate rules and regulations for the abovementioned establishments.

Moreover, when slaughter and preparation occurs at night, the Agriculture Secretary must authorize the examination and inspection of cattle and beef food products during that time⁹⁷. Careful inspection of all cattle offered for export to foreign countries is required by section 612 in order to ascertain whether such cattle are free from disease⁹⁸. Also, thorough inspection of carcasses, parts of carcasses and fresh, canned, salted, corned, packed, cured, or otherwise prepared meat intended and offered for export to any foreign country is mandatory⁹⁹. In addition, inspectors must prepare an official certificate clearly stating the condition of the inspected cattle¹⁰⁰.

Unless and until the owner procures certificate from an inspector certifying that the cattle were healthy at the time of inspection and that their meat is wholesome, no clearance will be granted to any vessel carrying fresh, salted, canned, corned, or packed beef meat for export to and sale in a foreign country from any port in the United States. However, the Secretary has discretion to waive this requirement¹⁰¹.

⁹⁶21 U.S.C. 608 (2004).

⁹⁷21 U.S.C. 609 (2004).

⁹⁸21 U.S.C. § 612 (2004).

⁹⁹21 U.S.C. § 615 (2004).

¹⁰⁰

¹⁰¹21 U.S.C. § 617 (2004).

To avoid adulteration or contamination, animals, carcasses, animal parts, meat and meat food products must not be prepared in the same establishment in which cattle are slaughtered¹⁰². Further, under section 620, no carcasses, meat or meat food products of cattle to be used as human food, can be imported in the United States if such articles are adulterated or misbranded¹⁰³. The carcasses, meat or meat food products must comply with inspection standards, the Humane Slaughter Act of 1958, as well as all other provisions of this regulation¹⁰⁴.

Once carcasses, meat or meat food products are imported into the United States, these articles will be deemed and treated as domestic articles subject to the other provisions of this chapter and the Federal Food, Drug, and Cosmetic Act (FD&C Act). These articles must be properly marked and labeled according to FD&C Act regulations for imported articles¹⁰⁵.

Section 620(b)(1) gives the Secretary of Agriculture authority to prescribe the terms and conditions for destruction of all cattle carcasses, meat, and meat food products that are imported contrary to this section. Additionally, section 620(b)(2) stipulates that articles found to be non-compliant with this chapter solely as a result of misbranding can be brought into compliance under the supervision of representatives of the Secretary. Non-compliance can be cured in order to avoid the destruction of the articles¹⁰⁶.

Section 620 also provides that the same inspection, sanitary, quality, species verification, and residue standards applied to products produced for human food in the United States applies to carcasses, meat and meat food products of cattle imported into the United States. Random inspections for species verifications

¹⁰²21 U.S.C. § 619 (2004).

¹⁰³The term “misbranded” refers to any carcass, meat, or meat food product with false or misleading labeling, or omits labeling information required by law.

¹⁰⁴21 U.S.C. § 620(a) (2004).

¹⁰⁵21 U.S.C. § 620(a) (2004).

¹⁰⁶21 U.S.C. § 620(b)(2) (2004).

and residues, and random sampling and testing of internal organs and fat of the carcasses for residues at the point of slaughter by the exporting country may be conducted to facilitate enforcement of this provision¹⁰⁷.

Each foreign country that imports carcasses, meat and meat articles into the United States is required to obtain certification from Secretary of Agriculture stating that the country uses reliable analytical methods to maintain compliance with United States standards for residues in meat articles. The Secretary of Agriculture must periodically review these certifications. The consideration of any application for a certification and the review of certifications must include the inspection of individual establishments to ensure that the inspection program of the foreign country is satisfying United States standards¹⁰⁸.

Section 620(g) permits the Secretary of Agriculture to prescribe terms and conditions under which cattle that have been administered an animal drug or antibiotic banned for use in the United States may be imported for slaughter and human consumption¹⁰⁹.

Section 620(2)(h) requirement contains a reciprocal meat inspection. At the behest of the Committee on Agriculture, the Committee on Ways and Means of the House of Representatives, the Committee on Agriculture, Nutrition, and Forestry, the Committee on Finance of the Senate, or at the initiative of the Secretary of Agriculture, the Secretary may act to determine whether a particular foreign country applies standards¹¹⁰ *for the importation of meat from the United States "that are not related to public health concerns about end-product quality that can be substantiated*

¹⁰⁷21 U.S.C. § 620(f) (2004).

¹⁰⁸21 U.S.C. § 620(f) (2004).

¹⁰⁹21 U.S.C. § 620(g) (2004).

¹¹⁰The term "standards" means inspection, sanitation, quality, species verification, residue, and other standards that are applicable to carcasses, meat and meat food products of cattle that are capable of use as human food. 21 U.S.C. § 620 (2004).

¹¹¹21 U.S.C. § 620(h) (2004).

Upon determination that a foreign country applies standards described above, the Secretary can begin consultation with the United States Senate and within thirty days after the determination, the Secretary and the United States Trade Representative are free to recommend to the President whether action should be taken to prohibit the country's importation into the United States of its carcasses, meat and meat food products.

Section 644 prohibits the buying, selling, transporting, or importing of dead, dying, disabled, or diseased animals, or any part of the carcasses of any animals that died otherwise than by slaughter. Whilst it also provides that the Secretary may authorize regulations to allow such transactions, transportation, or importation if the animals or their unwholesome parts are not used as human food¹¹².

The Federal Food and Safety Inspection Service (FSIS) is an agency of the United States Department of Agriculture (USDA). FSIS is responsible for ensuring that meat is safe, wholesome, and correctly labeled and packaged¹¹³. In this respect, certain regulations establish specific duties for the FSIS.

9 C.F.R. § 309 contains several inspection provisions that govern FSIS functions. Section 309.1 provides that all livestock offered for slaughter in an official pen must be inspected on the day of or before slaughter unless the Food Safety and Inspection Service (FSIS) Administrator has previously arranged for inspection to occur on a different day before slaughter¹¹⁴. Before livestock awaiting slaughter are permitted to enter into any department of the official slaughtering establishment or any department where edible products are

¹¹²21 U.S.C. § 644 (2004).

¹¹³http://www.fsis.usda.gov/About_Fsis/index.asp

¹¹⁴9 C.F.R. § 309.1(a) (2004).

handled, ante mortem inspections must be performed in pens of the establishment¹¹⁵.

Pursuant to C.F.R. § 309.2, livestock suspected to be diseased as a result of ante mortem inspection may be condemned after the carcass undergoes a post-mortem inspection. When an ante mortem inspection of livestock reveals a disease that would cause only part of the carcass to be condemned after post-mortem inspection, the livestock must be handled retained and identified as a suspect until the final post-mortem inspection is performed. If the post-mortem inspection reveals disease, the carcass must be marked for identification and disposed of accordingly¹¹⁶.

Moreover, seriously crippled or non-ambulatory disabled livestock must be identified as U.S. suspects and disposed of, unless they are required to be classed as condemned¹¹⁷. Livestock that are diseased with leptospirosis, anaplasmosis, tuberculosis, epithelioma of the eye, or anasarca are to be identified as U.S. Suspects and disposed of¹¹⁸.

Livestock suspected of anasarca infection can be set apart and held for treatment under official supervision. If upon completion of treatment the livestock is found to be disease-free, it may be released for any purpose¹¹⁹. If the livestock has diseases that the inspecting official believes are curable, such diseases may be treated under supervision. If the livestock is found to be disease-free after treatment, it may be released for slaughter or any other purpose¹²⁰.

¹¹⁵9 C.F.R. 309.1(b) (2004).

¹¹⁶9 C.F.R. 309.2(a) (2004).

¹¹⁷9 C.F.R. 309.2(b) (2004).

¹¹⁸9 C.F.R. 309.2(c),(d),(e), and (f) (2004).

¹¹⁹9 C.F.R. § 309.2(g) (2004).

¹²⁰9 C.F.R. § 309.2(g) (2004).

Each animal required to be treated as a U.S. Suspect is to be identified as such by an FSIS Program employee with an official device that can not be removed by anyone other than a Program employee¹²¹. Additionally, animals identified as U.S. Suspect on ante-mortem inspection must be isolated and slaughtered separately from other livestock kept at that establishment¹²².

Animals identified as U.S. Suspect on ante-mortem inspection, must be sent to slaughter with a form MP 402-2 on which the inspector is required to record the U.S. Suspect identification number, a description of the animal, and the disease for which the animal was categorized as suspect¹²³.

When any animal identified as U.S. Suspect is released for any purpose, the official suspect identification device may be removed only by a Program employee, who must report the removal to the area supervisor. When a suspect is to be released, the operator of the official establishment must first obtain permission for the removal of the animal from the local, State, or Federal livestock sanitary official¹²⁴.

Livestock found in a dead or dying condition at an official establishment must be identified as a U.S. Condemned and disposed of as soon as possible¹²⁵. If the ante mortem inspection of the livestock reveals any disease that would cause condemnation of their carcasses on post-mortem inspection, the livestock must be identified as U.S. Condemned and disposed of without delay¹²⁶. *Cattle with a temperature of 105° F or higher must be identified as U.S. Condemned. It must be condemned and disposed of*¹²⁷.

¹²¹9 C.F.R. § 309.2(m) (2004).

¹²²9 C.F.R. § 309.2(n) (2004).

¹²³9 C.F.R. § 309.2(o) (2004).

¹²⁴9 C.F.R. § 309.2(p) (2004).

¹²⁵9 C.F.R. § 309.3(a) (2004).

¹²⁶9 C.F.R. § 309.3(b) (2004).

¹²⁷9 C.F.R. § 309.3(c) (2004).

Livestock identified as U.S. Condemned are to be killed by the official pen and disposed of as soon as possible. Such animals can not be taken into the official establishment to be slaughtered or dressed, nor can they be taken into any department of the establishment used for edible products. The tags must not be removed, and the tag number must be reported to the veterinarian in charge by the inspector who affixed the tag and also by the inspector who supervised the disposal of the carcass. However, any livestock condemned because of a treatable disease, such as ketosis, vesicular diseases, anasarca, anaplasmosis, or pneumonia, may be isolated and held for treatment. The U.S. Condemned tag will be removed following treatment if the animal is found to be free of disease, and the animal can be used for any purpose¹²⁸.

During the slaughtering and preparation process, certain parts of the carcass are detached or removed from it. The head, tongue, tail, thymus gland, viscera, blood, and other parts severed from each slaughtered animal to be used in the preparation of meat food products or medical products must be identified with the rest of the carcass, until the post-mortem inspection of the carcass and its parts has been completed. The retention of ear tags, back tags, implants, and other identification devices affixed to the animal is required¹²⁹.

Testing procedures have been established to detect contamination with microorganisms. For example, official slaughtering establishments must test livestock for *Escherichia coli*. The establishments must collect samples from all chilled livestock carcasses, and the sampling frequency for cattle is 1 test per 300 carcasses, with a minimum requirement of one sample during each week of operation¹³⁰. *Exceptions are made for low volume establishments with an annual slaughtering volume of less than 100,000 carcasses.*

¹²⁸9 C.F.R. § 309.13 (2004).

¹²⁹9 C.F.R. § 310.2 (2004).

¹³⁰9 C.F.R. § 310.25 (2004).

Salmonella testing is also performed on raw meat in slaughtering and processing establishments. In order to enforce the provisions for microorganism detection, the FSIS is authorized to sample raw meat products in an individual establishment on an unannounced basis¹³¹.

B. European Union Directives on Inspection of Various Beef Production and Processing Facilities

Implementation of Directive 64/433/EEC is with the aim of standardizing health requirements for meat in slaughterhouses and cutting rooms and during storage and transportation¹³². In order to standardize the health requirements and improve intra-community trade in fresh meat, it is necessary to eliminate differences between health requirements of Member states.

Article 1 establishes the health rules for the production and placing on the market of fresh meat derived from domestic animals and intended for human consumption¹³³. Article 3 requires each Member State to ensure that carcasses, half carcasses, and quarter cuts: (1) come from a slaughter animal inspected ante-mortem by an official veterinarian; (2) have been slaughtered under satisfactory hygiene conditions; (3) have been inspected post-mortem by an official veterinarian; and (4) do not show any changes that would render the carcass unfit for human consumption or dangerous to human health; and (5) bear a health mark¹³⁴. Offal from carcasses must also comply with these requirements, and any other requirements for carcasses and smaller cuts of meat.

With respect to transportation of carcasses, half carcasses, and quarter cuts, Article 3 provides that these

¹³¹9 C.F.R. § 310.25 (2004).

¹³²The full title of this Directive is Council Directive 64/433/EEC of 26 June 1964 on health conditions for the production and marketing of fresh meat.

¹³³Council Directive 64/433/EEC applies to bovine, swine, sheep, goats, and domestic solipeds.

¹³⁴1964 J.O (121) 29.07.1964.

items must be accompanied during transportation by an accompanying commercial document. The document must be provided by the dispatching establishment, bear the veterinary approval number of the approved establishment and the month and year of freezing for frozen meat, and be retained by the consignee so that it can be furnished upon the request of the competent authority. Further, a health certificate is required for meat from a slaughterhouse in a restricted region or meat to be sent to another Member State¹³⁵.

In the instance of cold storage of fresh meat, such meat must be accompanied during transportation to its destination point by the accompanying commercial document or health certificate. Where meat is accompanied by a health certificate, the certificate must be completed by the official veterinarian. Moreover, in the case of importation, the certificate is to state the origin of the fresh meat and the veterinarian approval number of the cold store¹³⁶.

Pursuant to Article 4, the official veterinarian or an auxiliary must carry out post mortem inspection of meat.

Whereas, when the meat has lesions or appears to have deteriorated, the post mortem inspection must be carried out by the official veterinarian¹³⁷. *Once inspected, meat from the approved slaughterhouses and cutting rooms that has been judged fit for human consumption*

Article 5 makes it mandatory that the official veterinarian declares the following meat from animals unfit for human consumption: (1) meat from animals in which actinobacillosis, blackleg, tuberculosis, rabies, tetanus, acute salmonellosis, acute brucellosis, or botulism has been diagnosed; (2) meat showing acute lesions of broncho-pneumonia, pleurisy, peritonitis, arthritis, pericarditis, enteritis, or meningo-encephalo-

¹³⁵1964 J.O (121) 29.07.1964.

¹³⁶1964 J.O (121) 29.07.1964.

¹³⁷1964 J.O (121) 29.07.1964.

¹³⁸1964 J.O (121) 29.07.1964.

myelitis and confirmed by a detailed inspection and bacteriological examination and a search for residues with a pharmacological effect;¹³⁹ (3) meat infected by sarcocystosis, cysticercosis; (4) meat producing a positive reaction to tuberculin;¹⁴⁰ and (5) and meat producing a positive reaction to brucellosis¹⁴¹.

In addition, Article 5 establishes that the official veterinarian must declare meat unfit for consumption that is derived from animals that are: (1) dead, stillborn or unborn; (2) slaughtered too young with edematous meat; (3) showing signs of emaciation or advanced anemia; and (4) showing multiple tumors, abscesses or serious injuries in different areas of the carcass or in different viscera¹⁴². Also, the following must be declared unfit for human consumption: (1) parts of the carcass showing signs of major serious hemorrhaging, localized abscesses or localized contamination; (2) offal and viscera with pathological lesions of infectious, parasitic, or traumatic origin; (3) meat that is feverish, or shows serious abnormalities in color, smell, consistency, or taste; (4) offal that has not undergone post mortem inspection; and (5) blood derived from any animal meat declared unfit for human consumption or blood contaminated by stomach contents¹⁴³.

Article 5 further provides that the following must also be declared unfit for human consumption by the official veterinarian: (1) meat from animals that have been administered any prohibited substances; (2) meat containing residues of unauthorized substances, or residues of medicinal products, antibiotics, pesticides, or other substances that are harmful to human health; (3) the liver and kidneys of animals more than two years old from regions where there is a generalized presence of heavy metals in the environment; and (4) meat

¹³⁹On the other hand, where the special inspections and examinations are favorable, the carcasses may be declared fit for human consumption after parts unfit for consumption have been removed.

¹⁴⁰However, where tuberculous lesion has been found in the lymph nodes of the same organ or part of the carcass only the affected organ or part and the associated lymph nodes must be declared unfit for human consumption.

¹⁴¹1964 J.O (121) 29.07.1964.

¹⁴²1964 J.O (121) 29.07.1964.

¹⁴³1964 J.O (121) 29.07.1964.

that has been treated with ionizing or ultraviolet radiation¹⁴⁴.

The official veterinarian must subject Cattle and meat food products to examination for residues of substances with a pharmacological action, the conversion products of such substances, and for other substances harmful to human health. If the examination reveals traces of residues in quantities which exceed permitted levels, the meat must be declared unfit for human consumption. In this vein, at least one reference laboratory must be designated per Member State to carry out the examination for residues¹⁴⁵.

Article 9 requires that each Member States ensures the presence of at least one official veterinarian in a slaughterhouse throughout the ante-mortem and post-mortem inspections. Moreover, an official veterinarian must be present at least once a day in a cutting plant to inspect the hygiene conditions and to record the fresh meat entering and leaving the plant. Article 9 also necessitates the regular presence of an official veterinarian in a cold store and in an approved packaging center¹⁴⁶.

Under Article 10, each slaughtering, cutting, cold store, and packaging establishment must obtain approval from the competent national authority of the Member State. Where hygiene is found to be inadequate despite attempts to remedy the situation, the competent national authority may be authorized by the Member State to suspend approval. Following suspension of approval, if the operator of the establishment does not remedy the situation within the period specified, the competent national authority may withdraw approval of the establishment. The other Member States and the Commission are to be informed of the suspension or withdrawal of approval of any establishment¹⁴⁷.

¹⁴⁴1964 J.O (121) 29.07.1964.

¹⁴⁵1964 J.O (121) 29.07.1964.

¹⁴⁶1964 J.O (121) 29.07.1964.

¹⁴⁷1964 J.O (121) 29.07.1964.

Article 11 provides that Member States must delegate the task of collecting the results of the official veterinarian's ante-mortem and post-mortem inspections for diagnosis of diseases transmissible to humans to a central agency. Where such a disease is diagnosed, this diagnosis must be communicated as soon as possible to the competent veterinary authorities responsible for supervision of the herd from which the animal originated. Member States must submit to the Commission information on certain diseases, particularly in cases where the diseases are transmissible to man have been diagnosed¹⁴⁸. In order to ensure their access to establishments, Article 12 enables veterinary experts to conduct on-site visits of slaughtering, cutting, cold store, and packaging facilities to ensure uniform application of the rules and regulations set forth in this Directive. Where there is suspicion of non-compliance, Article 14 authorizes the official veterinarian to undertake any veterinary inspection deemed appropriate to investigate the matter¹⁴⁹.

Clear cut rules have been laid out for ante mortem health inspections under Chapter VI of Council Directive 64/433/EEC. Pursuant to Chapter VI animals must undergo ante-mortem inspection less than twenty four hours after their arrival in the slaughterhouse or less than twenty four hours before slaughter. Each animal intended for slaughter must bear a mark identifying its origin¹⁵⁰.

The ante mortem inspection must determine whether the animals have contracted or show symptoms of a communicable disease and whether they show symptoms of a disease likely to render their meat unfit for human consumption. If animals are suspected of having a disease that will render its meat unfit for human consumption, slaughter of the animal must be delayed until the animal undergoes an in-depth examination and diagnosis. In the event that a post mortem inspection is needed to conclusively diagnosis the animals,

¹⁴⁸1964 J.O (121) 29.07.1964.

¹⁴⁹1964 J.O (121) 29.07.1964.

¹⁵⁰1964 J.O (121) 29.07.1964.

the official veterinarian can request that the animals are slaughtered separately¹⁵¹.

Chapter VII mandates that slaughter animals brought into slaughter premises must be slaughtered immediately and bleeding, flaying, dressing and evisceration must be carried out in a way which avoids any contamination of meat. The chapter also provides that blood intended for human consumption must be collected in clean containers, and must be stirred with hygienic instruments. Further, uninspected carcasses and offal must not come in contact with carcasses already inspected, and the blood or offal of several animals collected in the same container before the completion of the post-mortem inspection must be declared unfit for human consumption if the carcass of one of the animals is declared unfit for human consumption¹⁵².

Chapter VII provides that all animals, animal parts and blood of animals must undergo a post mortem inspection immediately following slaughter to determine its fitness for human consumption. The following procedures must be performed during the post mortem inspection: (1) visceral inspection of the slaughtered animal and its organs; (2) palpation of the organs; (3) incision in the slaughter room of organs, which have lesions that may contaminate the carcass; (4) investigation of abnormal consistency, odor, color, smell. Moreover, the official veterinarian must conduct a visual inspection of head, throat, and internal organs¹⁵³.

Chapter XI lays specifies the requirements for health marking. Health marking is done under the supervision of the official veterinarian. The health mark must be an oval mark at 6.5 centimeters wide by 4.5 centimeters

¹⁵¹1964 J.O (121) 29.07.1964.

¹⁵²1964 J.O (121) 29.07.1964.

¹⁵³1964 J.O (121) 29.07.1964.

high bearing the initials of the consigning country in capital letters and the veterinary approval number of the establishment¹⁵⁴.

Council Directive 72/462/EEC was drafted on December 12, 1972 in order to specify the rules on importation of bovine, swine, and fresh meat from countries that are not part of the European Union, or third countries as they are referenced in this Directive¹⁵⁵.

Article 4 declares that the European Union will from time to amend lists of countries approved for importation of bovine animals and fresh meat. In order to determine a slaughterhouse, cutting plant, or cold store may appear an approved list, consideration should include: (1) the third country's guarantees to comply with this Directive; (2) the third country's regulations pertaining to animals for slaughter and substances which may affect the wholesomeness of the meat; and (3) the organization of the meat inspection services of the third country¹⁵⁶.

Article 5 authorizes on-the-spot inspections by veterinarians of Member States and the European Commission to verify whether the provisions of the Directive are being observed, and provides that these inspection cost are paid by the European Community¹⁵⁷.

¹⁵⁴1964 J.O (121) 29.07.1964.

¹⁵⁵The full name of the Directive is Council Directive 72/462/EEC of 12 December 1972 on health and veterinary inspection problems upon importation of bovine animals and swine and fresh meat from third countries.

¹⁵⁶1972 O.J. (L 302) Art. 4.

¹⁵⁷1972 O.J. (L 302) Art. 5.

Chapter 2 states that Member States must typically authorize the importation of animals from non-Member States only under these conditions: (1) the animals are free from any disease to which animals are susceptible; and (2) animals have been vaccinated during the preceding twelve months against diseases that are transmissible to other animals. Further, Article 11 provides that Member States can authorize the importation of bovine animals and swine only on the production of a certificate drawn up by an official veterinarian of the exporting non-Member State. Pursuant to Article 12, Member States must ensure that bovines are inspected by the official veterinarian when they arrive in the territory of the Community¹⁵⁸.

In addition, Article 12 prohibits animals from entering the Community if during the inspection it is found that: (1) the animals do not originate from the territory of a third country contained in the list; (2) the animals are infected with or are suspected of being infected with a contagious disease; or (3) the conditions established in this Directive have not been complied with by the exporting non-Member State. The Member State that inspected the animals denied entry in the Community is allowed to take measures such as slaughter, sending back animals, or quarantining animals to ensure the health and safety of the animals within its borders. In the event that animals are denied entry and measures previously mentioned are taken, the exporter or importer is liable for all expenses incurred and will not be compensated from the State¹⁵⁹.

Article 13 stipulates that imported animals must be slaughtered not later than three working days after their entry into the slaughterhouse. Additionally, Article 17 requires Member States to authorize imports of fresh meat cut in halves or quarters only the parts can be reconstructed as the entire carcass of each animal. This provision ensures that diseased parts have not been removed. All fresh meat must have undergone a post-mortem health inspection carried out by an official veterinarian to determine that it is suitable for

¹⁵⁸1972 O.J. (L 302) Arts. 11, 12.

¹⁵⁹1972 O.J. (L 302) Art. 12.

slaughter and exportation to the European Community. Such meat must be accompanied by a public health certificate and stored and transported under satisfactory hygiene conditions¹⁶⁰. The meat must also be inspected upon arrival into territory of the European Community¹⁶¹.

Article 20 necessitates that Member States prohibit the importation of: (1) fresh meat containing residues of estrogenous or thyrostatic substances, antibiotics, antimony, arsenic, pesticides or other substances likely to render the meat harmful to human health¹⁶²; (2) fresh meat treated with ionizing or ultraviolet rays, (3) fresh meat with any form of tuberculosis; and (4) fresh meat from animals which found to have tuberculosis or cysticerci. Article 22 provides that Member States must authorize fresh meat to be imported only on presentation of an animal health certificate and a public health certificate furnished by an official veterinarian of the exporting country¹⁶³.

In connection with contagious diseases, Article 28 provides that if a contagious animal disease thought could possibly endanger the health of the livestock of one of the Member States, erupts in a non-Member country, the Member State concerned is authorized to prohibit the importation of animals whether imported directly or indirectly through another Member. An identical rule applies to a contagious animal disease which can be carried by fresh meat and endanger the public health or the health of the livestock in one of the Member States¹⁶⁴.

On December 14, 1994, Council Directive 94/65/EC was established to create a framework for

¹⁶⁰1972 O.J. (L 302) Art. 17.

¹⁶¹1972 O.J. (L 302) Art. 23.

¹⁶²These substances must exceed permitted levels in order to be prohibited.

¹⁶³1972 O.J. (L 302) Arts. 20, 22.

¹⁶⁴1972 O.J. (L 302) Art. 28.

European Community regulation of the minced meat and meat preparations¹⁶⁵. Conditions for inspection, production, marking, labeling, and packaging are laid out in this directive.

Article 3 requires that fresh minced meat obtained from bovine animals must satisfy these requirements to be traded: (1) it must have been inspected; (2) it must have been marked and labeled; (3) it must be transported by an accompanying commercial document from the dispatching establishment, and (4) frozen meat must bear the veterinary approval number of the production plant and the month and year of freezing¹⁶⁶.

Minced meat that is frozen or deep frozen must meet these requirements: (1) it must come from fresh boned meat that has been stored no longer than eighteen months¹⁶⁷; (2) the fresh meat source of the minced meat that has been chilled, must be used within no more than six days after slaughter of the animals¹⁶⁸; (3) the minced meat must have undergone cold treatment within a period of not more than one hour after wrapping; and (4) the minced meat must be packaged properly. In addition, the fresh minced meat must be chilled and cooled to an internal temperature below +2°C in the shortest time possible, and deep frozen minced meat must be deep frozen and cooled to an internal temperature below -18°C in the shortest time possible¹⁶⁹.

Annex 1 contains special conditions of approval for establishments processing minced meat. In order to receive approval, production plants must have a room for mincing and wrapping that is separate from the cutting room. The room for mincing and wrapping meat must be equipped with a thermometer or recording

¹⁶⁵The full title of the Directive is Council Directive 94/65/EC of 14 December 1994 laying down the requirements for the production and placing on the market of minced meat and meat preparations.

¹⁶⁶1994 O.J. (L 368) 31.12.1994.

¹⁶⁷This rule applies to veal and beef.

¹⁶⁸With respect to boned, vacuum-packed beef and veal the time period extends to no more than fifteen days after slaughter of the animals.

¹⁶⁹1994 O.J. (L 368) 31.12.1994.

telethermometer. However, only the competent authority may authorize the approval of an establishment in which meat is minced in the cutting room, provided that the mincing is carried out in a clearly separate area of the cutting room¹⁷⁰. Also, the room for mincing and wrapping meat must contain refrigeration equipment capable of reaching the cooling temperatures stated above¹⁷¹.

Chapter II of Annex 1 requires examination of meat before mincing occurs, and removal and condemnation of all soiled parts before mincing. It further establishes that minced meat may not be obtained from scrap cuttings so as to ensure the quality and wholesomeness of the meat produced. In particular, minced meat may not be prepared from muscles of the head, the non-muscular part of the linea alba, the carpus and tarsus region, and bone scrapings. The muscles of the diaphragm and of the masseter may be used only after an investigation for cysticercosis¹⁷².

Chapter IV of Annex 1 provides specific guidelines for the production of meat preparations. The preparation of meat must occur under temperature control, and meat preparations must be wrapped in such a way as to obviate any risk of contamination. Further, meat preparations may be deep-frozen only once, and they are to be traded within an eighteen month time span¹⁷³.

Pursuant to Chapter V, meat production plants in the business of mincing meat and meat preparations must be inspected by the competent authority to monitor the following: (1) the hygiene of the premises; (2)

¹⁷⁰1994 O.J. (L 368) 31.12.1994.

¹⁷¹The fresh minced meat must be chilled and cooled to an internal temperature below +2°C in the shortest time possible, and deep frozen minced meat must be deep frozen and cooled to an internal temperature below -18°C in the shortest time possible.

¹⁷²1994 O.J. (L 368) 31.12.1994.

¹⁷³1994 O.J. (L 368) 31.12.1994.

sample collection of the products that meet the aforementioned requirements; (3) the microbial condition of the minced meat and meat preparations, (4) the appropriate health markings; and (5) hygienic storage and transport conditions¹⁷⁴. In addition, Chapter 6 provides that minced meat and meat preparations must have a health mark on the wrapping or packaging certifying that the items meet the requirements of this Directive. Chapter 7 establishes that minced meat and meat preparation wrapping and packaging must be impenetrable in order to prevent the entrance of substances that are harmful to human health¹⁷⁵.

C. United States Provisions for Residue Testing

In addition to inspection, residue testing is also vital to the production of safe, wholesome beef. Section 138(a) of 7 U.S.C. authorizes the Secretary of Agriculture to administer a National Laboratory Accreditation Program that determines the minimum quality and reliability standards for laboratories conducting residue testing of agricultural products or making claims to the public concerning chemical residue levels on agricultural products¹⁷⁶.

Further, the Secretary of Health and Human Services is responsible for approving state agencies or private nonprofit entities as accrediting bodies to implement certification and quality assurance programs¹⁷⁷. To gain accreditation, a laboratory is required to submit an application to the Secretary of Health and Human Services¹⁷⁸.

D. European Union Rules for Monitoring Residues in Meat

¹⁷⁴1994 O.J. (L 368) 31.12.1994.

¹⁷⁵1994 O.J. (L 368) 31.12.1994.

¹⁷⁶7 U.S.C. 138(a) (2003).

¹⁷⁷7 U.S.C. 138(c) (2003).

¹⁷⁸7 U.S.C. 138(d)(1) (2003).

Council Directive 96/23/EC was established on April 29, 1996 to lay down measures for monitoring substances and residues in live animals and animal products¹⁷⁹. Article 3 prescribes monitoring plans for the detection of residues or substances.

The production process of animals and the production of primary products of animal origin must be monitored for the purpose of detecting the presence of residues and substances categorized by “Group A” and “Group B” of this Directive in live animals, their excrement, body fluids, tissue, animal products, animal feed, and drinking water. Group A substances have an anabolic effect. The unauthorized substances include stilbenes, stilbene derivatives, stilbene salts and esters, antithyroid agents, steroids, resorcylic acid lactones, zeranol, and beta-agonists¹⁸⁰.

Group B substances are divided into three categories of veterinary drugs and contaminants. The first category includes antibacterial substances such as sulphonamides and quinolones. The second class comprises other veterinary drugs, such as antihelmintics, anticoccidials such as nitroimidazoles, carbamates, pyrethroids, sedatives, non-steroidal anti-inflammatory drugs, and other pharmacologically active substances. The third category consists of other substances and environmental contaminants, including organochlorine compounds, organophosphorus compounds, chemical elements, mycotoxins, and dyes¹⁸¹.

Article 4 requires Member States to designate the inspection duties to a central public department, so that fraudulent use of substances on stock farms may be discovered. According to Annex III, the inspection

¹⁷⁹The full title of the Directive is Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products.

¹⁸⁰1996 O.J. (L 125) 0010-0032.

¹⁸¹1996 O.J. (L 125) 0010-0032.

agency must adopt a residue control plan aimed at revealing the reasons for residue hazards in foods of animal origin on farms and in slaughterhouses. Wherever official samples are taken, sampling must be unforeseen, unexpected and effected at no fixed time and on no particular day of the week, so as to maintain the element of surprise¹⁸². With respect to Group A substances, inspections should be carried out with an eye toward detecting illegal administration of prohibited substances and the abusive administration of approved substances. The samples must be identified in consideration of these minimum criteria: age, sex, species, fattening system, available background information, and all evidence of misuse and abuse of Group A substances. For Group B substances, inspections should be carried out with the specific aim of controlling the compliance with maximum residue limits for residues of veterinary medicinal products and other contaminants¹⁸³.

Another European Union guideline for monitoring residues in meat and meat products were passed on February 23, 1998. Commission Decision 98/179/EC prescribes the procedures for official sampling of residues and substances that are illegally administered to cattle intended for human consumption and for controlling compliance with the maximum residue limits for residues of veterinary drugs and maximum levels of pesticides. The Annex to the Decision lays out the precise rules for monitoring residue and substance sampling as follows. The competent authority is tasked with the duty of designating an agency to take and organize the transport of the official control samples¹⁸⁴. The analysis of the samples is to be conducted in laboratories approved for official residue control, and regular proficiency testing schemes must be implemented to routinely check the competence of the laboratories¹⁸⁵.

¹⁸²1996 O.J. (L 125) 0010-0032.

¹⁸³1996 O.J. (L 125) 0010-0032.

¹⁸⁴1988 O.J. (L 65) 31-34.

¹⁸⁵1988 O.J. (L 65) 31-34.

Section 2.1 of the Annex states that samples must be random and unforeseen. All Member States must ensure the element of surprise in the checks. Random sampling should be carried out at varying intervals throughout the whole year, because a number of substances are only administered in a particular season¹⁸⁶.

VII.

Comparison of the United States' and the European Union's Approaches to Beef Regulation

An examination of the United States and the European Union regulation on cattle farming and beef production and processing reveals some notable similarities and differences. After summarizing the existing law concerning the regulation of the beef industry, there is a foundation for comparison. This section entails a brief comparison of the two systems. The analysis will explore the quality of the legislative drafting, the likelihood of implementation, the adequacy of consumer protections, the hortatory or compulsory nature of the measures, and the requirements of record retention.

The first area of review is the animal drug regulatory schemes. One marked difference in the pertinent American and the European Union rules is that the United States permits the administration of growth hormones to cattle intended for use as human food, whereas the European Union has banned such practices. In this area of regulation, both the United States and the European Union have drafted well written, clearly articulated, and easy to comprehend rules.

¹⁸⁶1988 O.J. (L 65) 31-34.

For example, the American Federal Food, Drug & Cosmetic Act explicitly indicates the hormones and growth promoters that are federally approved, and goes on to specify the permissible uses and dosages of the approved drugs. For example, estradiol valerate and norgestomet can be implanted in combination to synchronize estrus or ovulation¹⁸⁷. The laws are fairly specific in many respects as well. They indicate whether the drugs are to be administered as injections or implants. Express details provide that certain drugs are only to be administered to certain types of cattle. For instance, 10 mg of estradiol benzoate may be administered to suckling beef calves, and 20 mg for steers and heifers fed in confinement for slaughter¹⁸⁸. The European Union also expressly states its proscription of the use of growth hormones, and the specific methods of administration where the utilization of hormones is permitted for therapeutic purposes. For example, Member States may authorize the therapeutic administration to livestock of testosterone, progesterone, and their derivatives that readily yield the parent compound on hydrolysis after absorption. The Directives also clarify that hormonal, thyrostatic, and beta-agonists are all prohibited for use as growth enhancing drugs¹⁸⁹. The rules leave little room to argue that certain drugs that are used illegally to increase weight gain were not clearly prohibited as they were not hormones per se.

With respect to likelihood of implementation, both the United States and the European Union's regulations contain loopholes that may allow for abuse of the prohibitions and half-hearted implementation of the rules. However, the European Union's laws are more likely to achieve the desired prohibitions, because farmers are not authorized to possess or administer hormonal drugs that are only allowed for therapeutic uses but that can also be administered for growth promotion¹⁹⁰. Only official veterinarians, their supervisees, and

¹⁸⁷12 U.S.C. § 522.850 (2003).

¹⁸⁸12 U.S.C. § 522.841 (2003).

¹⁸⁹1996 O.J. (L 125) Art. 4.

¹⁹⁰2003 O.J. (L 262) 17-21.

other authorized persons are allowed to administer such drugs for therapeutic purposes, and farmers are prohibited from holding beta-agonists. Moreover, veterinary medicinal products banned for use as growth promoters can not be administered by implant, but must be administered by injection or for the treatment of ovarian dysfunction in the form of vaginal spirals¹⁹¹.

It is important to note that the growth enhancing drugs have permissible uses in both the United States and the European Union, hence they are available on the market and can be purchased legally in some circumstances. Thus, the possibility of them being used illegally in incorrect dosages, for unintended uses, and by unauthorized persons exists in both places as well. However, the European Union enactments contain more detailed monitoring provisions that mandate surprise inspections animals, their excrements, bodily fluids, drinking water, and stables in order to test for residues of prohibited drugs and substances¹⁹². This provides more incentive for livestock producers to implement the rules.

In addition, the laws can be compared according to their effectiveness in consumer protection. The United States laws prohibit the administration of certain growth hormones in unsafe ways. For instance, administration of estradiol valerate and norgestomet combinations are prohibited in cows that produce milk for human consumption¹⁹³, and this provision is included in order to preserve the quality and wholesomeness of the milk supply. Also, these implants must be removed on the tenth day and collected and burned¹⁹⁴ in order to avoid exceeding the approved dosages for animals intended for human consumption.

¹⁹¹1996 O.J. (L 125) Art. 4.

¹⁹²1996 O.J. (L 125) Art. 8.

¹⁹³12 U.S.C. § 522.850 (2003).

¹⁹⁴12 U.S.C. § 522.850 (2003).

The European Union operates under the premise that growth promoting hormones are dangerous to human health, and thus there are no tolerable daily intakes for many of them¹⁹⁵. In order to prevent treatment of cattle intended for human consumption, Council Directive 96/22/EC enumerates the hormones and their derivatives that are banned, and prohibits the importation of beef and beef food products treated with such drugs¹⁹⁶. The European Council has drawn up such provisions with the aim of ensuring that the beef supply of Member States is safe for human food.

In the United States and the European Union the laws on animal drugs are compulsory. Penalties apply to violators. Additionally, the European Union has provisions for record keeping. The official veterinarian is required to maintain records of animals treated by hormonal substances for therapeutic purposes¹⁹⁷. Farm animals undergoing such treatment must be clearly identified, and such treatment must be registered by the veterinarian responsible¹⁹⁸. The United States' rules do not contain such provisions.

The second area of comparison is the organic livestock production regulations. With respect to the quality of legislative drafting, the two systems are similarly adequate; however, the European Union regulations surpass the United States regulations in terms of depth and detail. For example, the United States Organic Foods Production Act lacks provisions on free range and open air exercise, prohibitions on overstocking of

¹⁹⁵Europa. *Hormones in Meat: Introduction, Food and Feed Safety* (2004), at http://europa.eu.int/comm/food/food/chemicalsafety/contaminants/hormones/index_en.htm.

¹⁹⁶1996 O.J. (L 125) 0003-0009.

¹⁹⁷1996 O.J. (L 125) Art. 4.

¹⁹⁸2003 O.J. (L 262) 17-21.

cattle in pastures, and advisory statements on the use of husbandry practices that encourage resistance to certain diseases and infections¹⁹⁹.

Furthermore, the likelihood of implementation of these rules is fair, because both the United States and the European Union have implemented sufficient monitoring mechanisms in order to increase the certainty of implementation and to detect residues of prohibited substances and drugs. The OFPA may be slightly more explicit with respect to monitoring provisions, because the provisions are included in the OFPA itself; whereas, the European Union has separate pieces of legislation, apart from Regulation No. 1804/1999, that provide for inspection of production and handling establishments and substance residue testing²⁰⁰.

For example, in the United States producers and handlers of organic livestock must create an organic plan²⁰¹. They must also certify to the Secretary, the State official, and the certifying agent on an annual basis that all agricultural products have been produced organically. Moreover, the OFPA provides for annual on-site inspections by the certifying agent of each farm and handling operation, and the rules require periodic residue testing by certifying agents of agricultural products produced on certified organic farms and in handling operations to determine whether they contain any pesticide or other nonorganic residue. Further, the OFPA requires that public access to certifying documents is granted²⁰². All of these procedures increase the likelihood that the regulation will be implemented and followed by producers.

¹⁹⁹The United States federal legislation may be less detailed, because the regulatory functions are shared by state and local governments such that areas that are unaddressed in federal laws may be covered in state or local laws.

²⁰⁰1999 O.J. (L 222) 24.8.1999.

²⁰¹Organic Foods Production Act of 1990, 7 U.S. § 6506 (2003).

²⁰²Organic Foods Production Act of 1990, 7 U.S. § 6506 (2003).

It is important to note that the European Union regulation for organic livestock production is less airtight than the American OFPA, because it allows conversion of nonorganically produced cattle associated with organic livestock. This provision opens the door to abuse, because there is a possibility that producers will market cattle as organically produced that have not been held in conversion for required twelve month period. Otherwise, there are significant measures in place to bolster the likelihood of implementation of the organic requirements.

The OFPA is not compulsory in either system in the sense that producers may elect to produce nonorganic livestock; but, once they seek organic certification the rules become compulsory. Both systems require record retention that is subject to inspection by the certifying agent as well. For example, in the European Union, record must be kept on all animals that are treated with veterinary medicinal products. Likewise, in the United States organic cattle farmers must keep records on all animals treated with medicines, on all feeds fed to the livestock, and on all animals so that they can be traced back to a specific farm.

The regulations on the human methods of slaughter in the United States and the European Union are very brief and substantially similar. The quality of the legislative drafting in both is sufficient, because they each succinctly and clearly state the approved methods of slaughter leaving very little room for variance in interpretation. Interestingly, the United States' rules are silent on the methods of slaughter for non-ambulatory livestock. Although, it is possible that the drafters may have intended to include them in the general reference to all livestock.

The legislation in the United States and the European Union are both wanting with regards to measures that increase the likelihood of implementation. Express provisions requiring random inspections of slaughterhouses would improve upon this inadequacy. The rules in both systems are compulsory, but they do not contain record keeping provisions. From an economic efficiency standpoint, the industries in the United States and the European may be more interested in allocating resources to ensure safe and wholesome beef and beef products than they are in tightly monitoring humane slaughtering practices.

The next topic of comparison is the regulation of BSE and other contagious diseases. Both the United States and the European Union have skillfully drafted, easy to interpret legislation in this area. In the case of the United States legislation, wide discretion is given to the Secretary to protect the meat supply in the United States. The Cattle Contagious Diseases Act and the BSE control measures clearly state that cattle produced for human consumption must be tested for the presence of communicable diseases²⁰³, and they provide for the seizure, treatment, and destruction of cattle found to be diseased and unfit for human consumption²⁰⁴. Moreover, the measures authorize the Agriculture Secretary to prohibit the importation and exportation of diseased livestock. Interestingly, the United States policies on BSE closely resemble those of the European Union.

As regards the European Union regulation for BSE, detailed rules are established for the determination of a Member State, third country, or region's BSE status, with a five category system of country classification ranging from BSE-free to high incidence of BSE²⁰⁵. The regulation gives precise information on the measures that must be taken to ensure that BSE is timely detected and eradicated. For instance, Each Member State

²⁰³21 U.S.C. § 114(a) (2004).

²⁰⁴7 U.S.C. 8306(a) (2003).

²⁰⁵2001 O.J. (L 147) Ann. 3.

must carry out a yearly program for monitoring BSE that involves rapid post mortem screening. The screening is to be performed on cattle showing signs of any form of disease or neurological disorder, cattle over thirty months of age, cattle that are found dead on the farm or during transport, and all animals slaughtered for human consumption²⁰⁶. Further, specified risk materials have been designated under both systems to prevent these animal parts from introducing BSE into the human food supply²⁰⁷. These examples illustrate the comprehensiveness of the regulations.

The likelihood of effective implementation is fairly great in the United States and in the European Union, because regulations have become more stringent in order to address the seriousness of the communicable diseases, such as BSE, that are currently threatening in the cattle population and the beef supply. In the United States and the European contexts, the regulations provide official inspectors and veterinarians with extensive authority to access production plants and slaughterhouses at all times of the day and night for random unannounced checks²⁰⁸. Furthermore, specific rules governing sampling and testing during the ante mortem and post mortem stages increase the likelihood of effective implementation of the procedures. Surveillance systems for the detection of BSE exist in America and Europe, and these systems have been created to aid implementation of detection and eradication measures²⁰⁹.

Increased incentive to implement the measures to detect and destroy cattle and beef food products infected

²⁰⁶2001 O.J. (L 147) Ann. 3.

²⁰⁷2001 O.J. (L 147) Ann. 5; Food Safety and Inspection Service, *Current Thinking on Measures that Could Be Implemented to Minimize Human Exposure to Materials that Could Potentially Contain the Bovine Spongiform Encephalopathy Agent*, NEWS AND INFORMATION (Jan. 15, 1999), at http://www.fsis.usda.gov/OA/topics/BSE_thinking.htm.

²⁰⁸Food Safety and Inspection Service, *Current Thinking on Measures that Could Be Implemented to Minimize Human Exposure to Materials that Could Potentially Contain the Bovine Spongiform Encephalopathy Agent*, NEWS AND INFORMATION (Jan. 15, 1999), at http://www.fsis.usda.gov/OA/topics/BSE_thinking.htm; 2001 O.J. (L 147) Ann. 3.

²⁰⁹Food Safety and Inspection Service, *Current Thinking on Measures that Could Be Implemented to Minimize Human Exposure to Materials that Could Potentially Contain the Bovine Spongiform Encephalopathy Agent*, NEWS AND INFORMATION (Jan. 15, 1999), at http://www.fsis.usda.gov/OA/topics/BSE_thinking.htm; 2001 O.J. (L 147) Ann. 2.

with BSE or other diseases that render the meat dangerous to human health is provided through government indemnity programs in the United States and the European Union. If farmers, handlers, and producers are indemnified for their losses, they are more likely to destroy cattle and beef that are found to be infected with diseases that cause them to be unfit for human consumption. Although no cases of BSE have been found in the United States, the European Union provides for compulsory reporting and examination of all cattle that exhibit clinical signs of BSE and all cattle that test positive for the disease²¹⁰.

The adequacy of consumer protection against BSE and other diseases is fairly decent in both the United States and the European Union. Strict detection and eradication standards have been implemented in both countries. It is important to note that none of the measures are absolute guarantees that no infected beef will enter the food supply. Samples are taken since it is economically infeasible to individually test all livestock that are placed on the market. Therefore, not all beef is tested for BSE and other diseases. However, as a general matter, the safety and quality of the beef supply is amply protected by the regulations in both systems.

In the United States and the European Union, the law requires immediate destruction of livestock that test positively for diseases that render meat unfit for human consumption²¹¹. In the European Union, Member States must ensure that no parts of the body of animals being screened for TSE are used for human food, animal feed, or fertilizers until the laboratory examination has been concluded with negative results²¹². Identical provisions have been implemented in the United States to protect consumers.

Since 1989, the United States Department of Agriculture's Animal and Plant Health Inspection Service

²¹⁰2001 O.J. (L 147) Ann. 5.

²¹¹9 C.F.R. § 53.2 (2004); 2001 O.J. (L 147) Ann. 3.

²¹²2001 O.J. (L 147) Ann. 3.

(APHIS) has banned the importation of live cattle and cattle products, such as rendered protein products, from countries where BSE exists with the intention of protecting American consumers from BSE exposure. In 1997, Food and Drug Administration prohibited the use of certain mammalian protein in the manufacture of ruminant animal feed in order to prevent the spread of BSE to cattle in the United States²¹³. These measures represent several of the numerous steps that the United States has taken to ensure consumer safety with respect to BSE.

The European Union has also instituted unique provisions to protect its citizens from BSE. For example, national reference laboratories and a Community Laboratory have been designated with the aim of ensuring uniformity and reliability of scientific analysis²¹⁴.

The regulations regarding BSE and other infectious diseases are compulsory in the United States and in the European Union. Interestingly, the European Union regulations allow Member States to undertake voluntary surveillance of TSE in higher risk animals, such as those originated from countries with indigenous TSE²¹⁵. This is an exception, because the relevant BSE and infectious disease regulations mentioned in this paper are all compulsory in nature.

The requirements for record retention are equally stringent under the United States and the European Union regulations. In particular, all detected cases of BSE must be recorded and reported to the USDA²¹⁶, in the

²¹³Food Safety and Inspection Service, *Current Thinking on Measures that Could Be Implemented to Minimize Human Exposure to Materials that Could Potentially Contain the Bovine Spongiform Encephalopathy Agent*, NEWS AND INFORMATION (Jan. 15, 1999), at http://www.fsis.usda.gov/OA/topics/BSE_thinking.htm

²¹⁴2001 O.J. (L 147) Ann. 10.

²¹⁵2001 O.J. (L 147) Ann. 3.

²¹⁶Food Safety and Inspection Service, *Current Thinking on Measures that Could Be Implemented to Minimize Human Exposure to Materials that Could Potentially Contain the Bovine Spongiform Encephalopathy Agent*, NEWS AND INFORMATION (Jan. 15, 1999), at http://www.fsis.usda.gov/OA/topics/BSE_thinking.htm.

case of the United States, and to the European Commission²¹⁷, in the case of European Union Member States. As no cases have been found in the United States, the European Union has defined rules for the reports of TSE. For instance, the information reported must entail the number, age distribution, geographical distribution of positive cases of BSE, as well as the year and month of birth for BSE cases born after the introduction of a ban on using ruminant protein in animal feed²¹⁸. Records of all positive cases must be retained for seven years.

The final subject of review is inspection regulations in the United States and the European Union. Regarding the quality of legislative drafting, the regulations in both systems are well written. The rules clearly articulate inspection requirements and leave very little, if any, room for differing interpretations. Additionally, in the United States and the European Union, the laws are fairly comprehensive in that they mandate inspections at various stages of the slaughtering and meat production process.

For example, in the United States the FMIA requires the following: (1) ante mortem inspections, (2) post mortem inspections, and (3) pre-packaging inspections. Subsequent inspections are required before beef and beef products that are offered for intrastate and interstate commerce and exportation, and sanitation inspections are required for all slaughtering, canning, packing, and similar establishments²¹⁹. The FMIA expressly states that inspections may be carried out randomly and without prior notice. Similar provisions exist in the European Union inspection regulations.

Furthermore, inspections of slaughtering and meat production facilities are to be carried out with an eye toward prescribing appropriate rules and regulations for the establishments. Perhaps, the FMIA could have

²¹⁷2001 O.J. (L 147) Ann. 4.

²¹⁸2001 O.J. (L 147) Ann. 4.

²¹⁹21 U.S.C. § 604 (2004).

been drafted to include specific guidance on the prescription of appropriate rules for the establishments to ensure uniformity of inspections standards. However, given that meat inspection duties in the United States are shared among federal, state, and local governments, a certain level of variance in the regulations is inevitable.

Concerning the comprehensiveness of the European Union's inspection regulations, Directive 64/433/EEC clearly states the requirements for inspection at different stages of the meat production process. For instance, the 64/433/EEC mandates ante mortem and post mortem inspections by the official veterinarian²²⁰. The drafting of this Directive is slightly more specific than its American counterpart.

64/433/EEC explicitly mandates that meat affected with certain conditions or derived from certain sources must be declared unfit for human consumption²²¹. These rules are stated together and more concisely. Specifically, it provides that meat from animals with such diseases as actinobacillosis, blackleg, rabies, tetanus, acute lesions of broncho-pneumonia, pleurisy, peritonitis, arthritis, pericarditis, enteritis, meningo-encephalo-myelitis must be declared unfit for human consumption. Directive 64/433/EEC also provides that meat must be declared unfit for consumption that is derived from animals that are stillborn, unborn, slaughtered too young, and emaciated, to name a few of the enumerated conditions²²².

The likelihood of implementation of the inspection regulations is fair in both systems. Mainly due to economic constraints that hinder thorough inspection of each slaughterhouse and meat plant, derogations occur and some are even permitted by the regulations. However, the inspection regulations of the United States and the European Union have built-in checks to increase the likelihood of implementation.

²²⁰1964 J.O (121) 29.07.1964.

²²¹1964 J.O (121) 29.07.1964.

²²²1964 J.O (121) 29.07.1964.

In the United States, several provisions of the FMIA are intended to monitor implementation of the inspection regulations. For instance, the requirements for inspections at various stages of the meat production process are built-in checks, which seek to ensure the safety and wholesomeness of the beef supply through repeat inspections before the meat reaches supermarkets. In addition, inspectors must prepare official certificates clearly stating the condition of inspected cattle²²³. Owners must obtain health certificates in order to gain clearance for vessels carrying beef for export from United States ports to foreign countries²²⁴.

Additional measures are contained in the FMIA to verify implementation of the inspection provisions. The Secretary of Agriculture must grant certification to all countries that import carcasses and beef products into the United States so as to verify that the country employs reliable analytical methods and comparable standards for detecting residues in meat. The review of certification applications necessarily entails the inspection of individual establishments to confirm that inspection programs in foreign countries comply with United States standards²²⁵.

Only designated employees are authorized to remove the official suspect identification device of animals identified as “U.S. Suspect” when the animals are released, and the removal must be reported to the area supervisor²²⁶. This provision is included in the FMIA as another built-in check intended to prevent the release of animals suspected of harboring diseases that may render them unfit for human consumption from entering the food supply.

When an animal identified as U.S. Suspect is released for any purpose, the official suspect identification

²²³21 U.S.C. § 617 (2004).

²²⁴21 U.S.C. § 617 (2004).

²²⁵21 U.S.C. § 620(f) (2004).

²²⁶9 C.F.R. § 309.2(n) (2004).

device may be removed only by a Program employee, who must report the removal to the area supervisor. When a suspect is to be released, the operator of the official establishment must first obtain permission for the removal of the animal from the local, State, or Federal livestock sanitary official²²⁷. Similarly, the tags for livestock identified as U.S. Condemned must not be removed, and the tag number must be reported to the veterinarian in charge by the inspector who affixed the tag and also by the inspector who supervised the disposal of the carcass²²⁸. *Alloftheseprovisionsareincludedtoincreasethelikelihoodofimplementation.*

In the European Union, Directive 64/433/EEC has built-in checks to improve the likelihood of implementation by Member States. For example, carcasses and beef items must be accompanied during transport by accompanying commercial documents. These documents are provided by the dispatching establishment and they must bear the veterinary approval number of slaughtering or processing plant. Also, a health certificate is required for meat from a slaughterhouse in a restricted region and meat that is sent from one Member State to another Member State²²⁹.

Directive 64/433/EEC requires the presence of an official veterinarian at least once a day in slaughterhouses, cutting plants, and cold stores. In each Member State, a central agency must collect the results of the official veterinarian's ante mortem and post mortem inspections for diseases transmissible to humans²³⁰. In addition, Directive 72/462/EEC authorizes on-the-spot inspections by veterinarians of Member States and the European Commission to verify whether the third countries that import fresh meat into the European Union meet specified standards, and provides that these inspection cost are to be paid by the European

²²⁷9 C.F.R. § 309.2(p) (2004).

²²⁸9 C.F.R. § 309.13 (2004).

²²⁹1964 J.O (121) 29.07.1964.

²³⁰1964 J.O (121) 29.07.1964.

Community²³¹.

Directive 94/65/EC requires that fresh minced meat that is to be traded must be transported by an accompanying commercial document from the dispatching establishment, and frozen meat must bear the veterinary approval number of the production²³². Commission Decision 98/179/EC requires all Member States conduct surprise checks to sample for residues and substances that are illegally administered to cattle. These checks must be random and unforeseen, and they must be performed at intervals throughout the year to test for substances that are only administered seasonally²³³. These provisions are included to increase the likelihood of implementation of the inspection regulations.

In the United States and the European Union the inspection regulations are equally adequate with respect to consumer protection provisions. In both systems, the requirements for inspection at various phases in the meat production process are included in order to ensure that safe and wholesome beef enters the food supply. Moreover, immediate destruction and disposal of animals, carcasses, and meat that is found to be unfit for human consumption is required in the United States and the European Union. Animals that have been condemned must be isolated and slaughtered separately in order to avoid contamination of healthy animals intended to be slaughtered for human consumption²³⁴.

Considering the large volume of cattle and beef products that enter and exit meat processing plants in the United States and the European Union, it is impossible for each animal or product to be tested before it is declared fit for consumption. For instance, in the United States the sampling frequency requirement

²³¹1972 O.J. (L 302) Art. 5.

²³²1964 J.O (121) 29.07.1964

²³³1988 O.J. (L 65) 31-34.

²³⁴21 U.S.C. § 604 (2004).

for official slaughtering establishments testing cattle for *escherichia coli* is 1 test per 300 carcasses, with a minimum requirement of one sample each week²³⁵. Clearly, economic limitations prevent the United States from testing each cattle or beef article that is produced. Despite reasonable economic justifications, there is still a small risk that contaminated meat will not be detected under these rules.

One feature of the European Union regulations that aim to ensure consumer safety are the explicit requirements in Directive 94/65/EC for freezing and chilling meat in order to avoid contamination with pathogens and microbes that would render the meat dangerous to human health. For example, fresh minced meat must be chilled and cooled to an internal temperature below +2°C in the shortest time possible, and deep frozen minced meat must be deep frozen and cooled to an internal temperature below -18°C in the shortest time possible²³⁶. Similar provisions are likely to be present in the state and local inspection regulations in the United States.

The inspection regulations in the United States and the European Union are of a compulsory nature. For live cattle, beef, and beef food products to be placed on the market, they must be inspected in order to ensure that they are safe and disease-free. Therefore, mandatory implementation of the rules is needed to protect American and European consumers.

Both the United States and the European Union have record-keeping requirements that allow them to trace cattle, from which beef food products are derived, back to the herd in case contagious diseases or other conditions are found upon inspection.

²³⁵9 C.F.R. § 310.25 (2004).

²³⁶1994 O.J. (L 368) 31.12.1994.b

VIII. Conclusion

Even though their approaches to regulation of the beef industry differ in several ways, both the United States and the European Union have established legislation that is generally effective in this area. This paper has sketched an overview of the regulations on animal drugs, organic livestock, humane slaughter methods, BSE and other contagious diseases, and inspection of beef production facilities in both legal systems. A brief comparison of the American and the European Union regulatory systems examined the quality of legislative drafting, the probability of implementation, the adequacy of consumer protections, the hortatory or compulsory nature, and the requirement of record-keeping. The analysis revealed that the regulations in each system seek to achieve fairly similar ends, though sometimes through different means.